IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

MEIJER, INC. and MEIJER DISTRIBUTION, INC., on behalf of themselves and all others similarly situated, *Plaintiffs,* *vs.* ALLERGAN PLC (f/k/a ACTAVIS PLC); ALLERGAN, INC.; ALLERGAN USA, INC.; ALLERGAN SALES, LLC; WARNER CHILCOTT LIMITED; WARNER CHILCOTT (U.S.), LLC; WARNER CHILCOTT SALES (U.S.), LLC; ZYDUS PHARMACEUTICALS USA INC.; and CADILA HEALTHCARE LIMITED, *Defendants.*	Civil Action No. 16-cv-3092 JURY TRIAL DEMANDED

COMPLAINT

Direct purchaser plaintiff, Meijer, Inc. and Meijer Distribution, Inc. (collectively, "Plaintiff" or "Meijer"), on behalf of itself and all others similarly situated, files this Class Action Complaint and Jury Demand against Defendants Warner Chilcott Limited; Warner Chilcott (U.S.), LLC; Warner Chilcott Sales (U.S.) (collectively "Warner Chilcott"); Allergan plc, formerly known as "Actavis plc"; Allergan, Inc.; Allergan USA, Inc.; Allergan Sales, LLC (collectively "Allergan," or together with Warner Chilcott, the "Scheme Defendants"); Zydus Pharmaceuticals USA Inc.; and Cadila Healthcare Limited (together "Zydus" or collectively with Allergan, the "Exclusion Payment Defendants"). Based on personal knowledge, the investigation of counsel, and information and belief, Plaintiff alleges as follows:

I. NATURE OF THE ACTION

1. This is a civil antitrust action seeking treble damages and other relief for the Defendants' unlawful impairment of competition to drugs in Warner Chilcott's Asacol franchise (Asacol (400mg), Asacol HD, and Delzicol). As alleged below, the Scheme Defendants, beginning with Warner Chilcott and continuing after the company became part of Allergan (f/k/a Actavis), used an extensive array of anticompetitive acts and practices as part of an overall scheme to improperly maintain and extend its monopoly power with respect to the Asacol franchise, to the detriment of Plaintiff and the classes of direct purchasers it seeks to represent, causing them to pay overcharges.

2. The Defendants' anticompetitive scheme is one of the most extensive, cynical, and ruthless in the history of the U.S. pharmaceutical industry. The scheme robbed purchasers of the benefits of generic competition by driving all of the Asacol (400mg) patients to two other products that did not face imminent generic competition, i.e., Asacol HD and Delzicol – products that had no independent therapeutic benefits for patients but instead created additional safety and convenience problems. The scheme included refusing the FDA's request to reformulate Asacol (400mg) by simply removing a potentially harmful ingredient from it; instead of reformulating as the FDA had requested, also putting a bogus capsule around Asacol (400mg) tablets in order to prevent generic Asacol (400mg) from being substitutable for the "new" branded product, Delzicol; withdrawing Asacol (400mg) from the market, once Delzicol was available, in order to force doctors and patients to switch to Delzicol; cannibalizing the sales of Asacol (400mg), i.e., switching the prescription base to Asacol HD and Delzicol before generic Asacol (400mg) could enter the market; gaming the regulatory system in order to cause uncertainty as to whether the FDA would approve any ANDA for generic Asacol (400mg); bribing doctors to switch prescriptions from Asacol (400mg) to Asacol HD, which contained twice as much of the

potentially harmful ingredient that had prompted the FDA's safety concern; switching prescriptions from Asacol (400mg) to the twice-as-much-harmful-ingredient Asacol HD by promoting the latter for off-label uses; improperly listing a patent in the FDA's Orange Book in order to allow Warner Chilcott to automatically block generic entry for up to 30 months; commencing and maintaining sham patent litigation against at least two generic manufacturers; and paying off another generic manufacturer in exchange for its delaying entry into the market. Warner Chilcott has already pled guilty to felony healthcare fraud with respect to some aspects of this scheme.

3. Asacol (400mg) was a delayed-release mesalamine formulation used to treat multiple forms of ulcerative colitis, a potentially debilitating condition affecting 238 out of 100,000 people in the United States. Patients on this drug typically remain on it for years, if not their entire lives. By 2004, it was one of the top 100 selling prescription drugs in the United States and was generating more than $300 million in annual U.S. sales for Proctor & Gamble Pharmaceuticals, Inc. ("Proctor & Gamble"). Warner Chilcott acquired the rights to Asacol (400mg) in 2009. By 2012, annual sales of Asacol (400mg) in the United States had grown to more than $570 million. Proctor & Gamble, and later Warner Chilcott, sold Asacol (400mg) at supracompetitive prices during this period because two patents blocked other manufacturers from selling a generic version of the drug.

4. The two patents protecting the drug expired on July 30, 2013, threatening Warner Chilcott's ability to sell Asacol (400mg) at supracompetitive prices. After that date, generic manufacturers would be able to compete for the first time. State generic-substitution laws would push Asacol (400mg) over the "patent cliff" – upon patent expiry in July 2013, Warner Chilcott

would quickly lose almost all of its sales to generic competitors selling Asacol (400mg) at a fraction of the brand price. But Warner Chilcott had other ideas.

5. On October 1, 2013, Actavis acquired Warner Chilcott. In performing due diligence for that acquisition, Actavis knew that Asacol (400mg) and another financially important Warner Chilcott drug, Loestrin 24 Fe, would soon be pushed over the patent cliff if Warner Chilcott had done nothing to impair generic competition. Actavis nevertheless pursued the acquisition, assuring its shareholders and potential investors that Warner Chilcott had embarked on a multifaceted scheme that would successfully protect these drugs from generic competition. For example, Sigurdur Oli Olafsson, Actavis' President of Global Generics, told investors in May 2012 that Actavis was "very impressed" with Warner Chilcott's anticompetitive scheme, which he euphemistically referred to as "the ever-greening line extension strategy."

6. Actavis was right. Warner Chilcott's scheme to impair generic competition has been, to date, very successful. But the scheme and it various parts flagrantly violate the Sherman Antitrust Act. Warner Chilcott thus lined its and its shareholders' pockets with money stolen from purchasers of Asacol franchise drugs. This lawsuit seeks recovery of those stolen funds on behalf of the purchasers of the Asacol franchise products. Defendants' unlawful Asacol scheme had multiple elements, many of which are independently unlawful, and all of which were part of an overall unlawful scheme.

7. **The Product Hop –** Before manufacturers of generic Asacol (400mg) could begin marketing their products, Warner Chilcott reformulated Asacol (400mg) into two products, Asacol HD and Delzicol, with the purpose and effect of preventing generic Asacol (400mg) from being substitutable for the "new" products at the pharmacy counter. The modifications that Warner Chilcott made to Asacol (400mg) to render generic Asacol (400mg) non-substitutable –

in one instance changing the dosage form from a tablet to a capsule (Delzicol), and in another instance changing the dosage strength from 400mg to 800mg (Asacol HD) -- had no safety, efficacy, or other benefit of any kind for patients. Warner Chilcott's sole motive in making these modifications to the product was to impair generic competition.

8. Once the FDA approved the reformulated versions of Asacol (400mg) – which Warner Chilcott marketed as Asacol HD and Delzicol – Warner Chilcott employed its army of sales force detailers to cannibalize the Asacol (400mg) prescriptions, i.e., to aggressively switch them to these new products. In a February 2013 investor conference call, Warner Chilcott's Chief Executive explained the purpose and effect of the product-hop:

> Generally, the generic company doesn't even get launched because the reference product will be Delzicol. . . . There won't be any Asacol out there. We've seen that happen with Doryx, when the generic company got the product approved and by that time the product had moved on . . . . As the reference product has changed and then moved on to either tablet or new dose form, there really isn't much to be substituted there.

Warner Chilcott Management Discusses Q4 2012 Results - Earnings Call Transcript, *available at* http://seekingalpha.com/article/1216961-warner-chilcott-management-discusses-q4-2012-results-earnings-call-transcript.

9. **The Off-Label Marketing and Bribes** – One of the reformulated products to which Warner Chilcott unlawfully "hopped" or switched the Asacol (400mg) prescription base was Asacol HD. Asacol HD is an 800mg version of Asacol (400mg). But the FDA approved Asacol HD to treat only the second of the three conditions for which the FDA had approved Asacol (400mg): *mildly* active ulcerative colitis; *moderately* active ulcerative colitis; and the *maintenance of remission* of ulcerative colitis. The other two conditions accounted for the vast majority of the Asacol (400mg) prescription base, with moderately active ulcerative colitis – the

only condition for which FDA approved Asacol HD – constituting less than 10% of the prescriptions.

10. Despite the FDA's specific refusal to approve Asacol HD for treating those conditions, Warner Chilcott systematically and unlawfully promoted Asacol HD to treat mildly active ulcerative colitis and maintenance of remission therapy. Warner Chilcott also bribed doctors to switch patients from Asacol (400mg) to Asacol HD. In April 2016, Warner Chilcott pled guilty to felony healthcare fraud (18 U.S.C. § 1347) for unlawfully paying kickbacks to prescribers of Asacol and Asacol HD (among other drugs) between October 2009 and September 2013.

11. **The Unlawful Patent Listing and Sham Litigation** – The other reformulated product to which Warner Chilcott unlawfully "hopped" or switched the Asacol (400mg) prescription base was Delzicol. Delzicol is essentially an Asacol (400mg) tablet placed inside a capsule. The capsule provides no medical or convenience benefits of any kind to patients, and is actually a disadvantage to patients because it is difficult to swallow. Warner Chilcott placed the tablets inside a capsule for the sole purpose of impairing generic competition. First, encapsulating the product made generic Asacol (400mg) tablets non-substitutable, thus requiring generic manufacturers to file new applications with the FDA to sell the generic product in capsule form. Second, encapsulating the product enabled Warner Chilcott to automatically prevent manufacturers of the generic product in the capsule formulation from entering the market for up to 30 months. Warner Chilcott acquired rights to a patent that claimed the capsule – just the capsule shell itself, not the drug product or active ingredient in capsule form – and then listed the patent in the FDA's Orange Book and asserted that it claimed the Delzicol drug product. By listing the patent in the Orange Book, Warner Chilcott automatically received up to 30 months of

freedom from generic competition when it commenced patent litigation against generic manufacturers based on their alleged infringement of that patent. Warner Chilcott's listing of the capsule patent in the Orange Book, and assertion that the patent claimed the drug product, was grossly improper: the patent claims only the capsules themselves, not the drug product or, indeed, any ingredient in it. And Warner Chilcott's ensuing patent litigation against the generic manufacturers was a sham, lacking any basis for alleging that the generic manufacturers' products infringed the patent on the capsules.

12. **The Exclusion Payment** – After successfully cannibalizing the Asacol (400mg) prescription base, Warner Chilcott faced a threat of generic competition for its "new" product, Asacol HD. Defendant Zydus Pharmaceuticals filed the first application seeking FDA approval for generic Asacol HD. Warner Chilcott filed a patent infringement suit in order to prevent Zydus from entering the market. After two years of litigation, Zydus agreed to delay entering the market until as late as July 1, 2016 in exchange for an unlawful pay-off from Warner Chilcott. The pay-off took the form of Warner Chilcott's agreeing not to compete against Zydus with an authorized generic version of Asacol HD.

13. As Defendants intended, their anticompetitive scheme and cornucopia of anticompetitive conduct had the effect of dissuading generic manufacturers from obtaining FDA approval for and marketing competing versions of Asacol (400mg). But for the scheme, a generic version of Asacol (400mg) would have entered the market no later than July 31, 2013. Being automatically substitutable for 100% of the units of branded Asacol (400mg), generic competitors would have captured 80% to 95% of Asacol (400mg) sales, at a small fraction of the brand price, delivering hundreds of millions of dollars in annual savings to purchasers.

14. Instead, Allergan continues to retain its original Asacol (400mg) profits under the Delzicol and Asacol HD brands. Allergan sold approximately $550 million of the two drugs in 2014 – at least eight times more than what it would have sold had Defendants not unlawfully impaired generic competition.

II. JURISDICTION AND VENUE

15. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by Plaintiff and members of the Classes (defined below) resulting from Defendants' unlawful impairment of generic competition. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1407, and 15 U.S.C. § 15.

16. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d). During the Class Periods, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the activity affecting interstate trade and commerce discussed below has been carried out in this District.

17. Defendants' conduct, as described in this complaint, was within the flow of, was intended to, and did have a substantial effect on the interstate commerce of the United States, including this District.

18. During the Class Periods, Warner Chilcott and Allergan (f/k/a Actavis) manufactured, sold and shipped Asacol (400mg), Asacol HD, and Delzicol in a continuous and uninterrupted flow of interstate commerce. The unlawful conduct in which the Defendants engaged had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

19. During the Class Periods each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce, including interstate wires, interstate electromagnetic spectrum, interstate railways, and the U.S. mail, to effect their unlawful conduct.

20. This Court has personal jurisdiction over each Defendant, because each Defendant – throughout the United States and including in this District – transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of their unlawful scheme and conspiracy. Defendants' unlawful conduct was directed at, and had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

III. PARTIES

A. Plaintiff

21. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. are corporations organized under the laws of the State of Michigan, with their principal place of business located in Grand Rapids, Michigan 49544. Meijer is the assignee of the claims of the Frank W. Kerr Co., which, during the Class Periods, as defined below, purchased Asacol HD and Delzicol directly from the Scheme Defendants and suffered antitrust injury as a result of the anticompetitive conduct alleged herein. Frank W. Kerr Co. resold to Meijer some of the Asacol HD and/or Delzicol that it purchased from Scheme Defendants during the relevant period.

B. Defendants

22. Defendant Allergan plc ("Allergan") is a public limited company incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. Allergan maintains a place of business within the United States at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054. Allergan was known as "Actavis plc" ("Actavis") until June 15, 2015, when it began operating under its

current name. Allergan markets branded and generic pharmaceuticals throughout the United States and has commercial operations in the United States and approximately 100 countries around the world. Allergan became a successor in interest to Warner Chilcott plc and Proctor & Gamble Pharmaceuticals Inc. when it acquired Warner Chilcott plc on October 1, 2013.

23. Allergan, Inc. is incorporated under the laws of Delaware with its principal place of business at 2525 Dupont Drive, Irvine, California 96212.

24. Allergan USA, Inc. is incorporated under the laws of Delaware with its principal place of business at 2525 Dupont Drive, Irvine, California 96212.

25. Allergan Sales, LLC is a California limited liability corporation with its principal place of business at 2525 Dupont Drive, Irvine, California 96212.

26. Warner Chilcott Limited is a wholly-owned subsidiary of Allergan plc and is incorporated under the laws of Bermuda with its principal place of business at Canon's Court, 22 Victoria Street, Hamilton HM 12, Bermuda.

27. Warner Chilcott (US), LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

28. Warner Chilcott Sales (US), LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

29. Zydus Pharmaceuticals USA Inc. ("Zydus") is a privately held corporation under the laws of New Jersey with its principal place of business at 73 Route 31 N., Pennington, New Jersey 08534. Zydus is a wholly-owned subsidiary of Cadila Healthcare Limited. Zydus markets and distributes generic drugs for sale throughout the United States.

30. Cadila Healthcare Limited is a corporation organized under the laws of India with its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad 380015, India. Cadila Healthcare Limited works in concert with Zydus to develop, manufacture, and market pharmaceutical products throughout the United States.

IV. THE PRESCRIPTION DRUG MARKETPLACE AND REGULATORY FRAMEWORK

A. Characteristics of the Pharmaceutical Marketplace

31. The marketplace for the sale of prescription pharmaceutical products in the United States contains a significant feature that can be exploited by manufacturers in order to extend a monopoly in the sale of a particular pharmaceutical composition. In most industries, the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's choice of products and, consequently, manufacturers have a strong incentive to keep prices low and to reformulate their products only when doing so is likely to increase consumer welfare.

32. The pharmaceutical marketplace, by contrast, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including the Asacol franchise products, to patients without a prescription. The prohibition on dispensing certain products without a prescription introduces a "disconnect" in the pharmaceutical marketplace between the payment obligation and the product selection. The patient (and in many cases his or her insurer) has the obligation to pay for the product, but the patient's doctor chooses which product the patient will buy.

33. Many pharmaceutical manufacturers, including Allergan (f/k/a Actavis) and its wholly-owned subsidiary Warner Chilcott, exploit this feature of the pharmaceutical

marketplace. The so-called "brand manufacturers" (*i.e.*, the manufacturers of branded, as opposed to generic, pharmaceuticals) employ large forces of sales representatives, known as "detailers," who visit doctors' offices in an effort to persuade them to prescribe the manufacturer's products. Importantly, these detailers do not advise the doctors of the cost of the branded products. Studies show that doctors typically are not aware of the relative costs of branded prescription drugs and that, even when doctors are aware of the relative cost, they are insensitive to price differences because they do not pay for the products. The result is a marketplace in which price often plays a comparatively unimportant role in product selection.

34. In situations in which two manufacturers each sell a drug that serves a similar medical function and each manufacturer uses a significant detailer force, those products are often sold at very similar, high prices, thus eliminating any consumer benefit from that "competition." This is in stark contrast to the situation in which a competitor sells a generic version of the branded drug. In that case, the generic price is significantly lower than the brand price, and purchasers benefit as Congress intended by the Hatch-Waxman Act, discussed below.

35. When the relative importance of the price between two products is low, the price elasticity of demand—the extent to which sales go down when price goes up—is also low, which in turn gives brand manufacturers the ability to raise or maintain price substantially above competitive levels without losing so many sales that the price increase becomes unprofitable. The ability to raise price above competitive levels without losing so many sales as to make the price increase unprofitable, is referred to by economists and antitrust courts as market power or monopoly power. Thus, the net result of the pharmaceutical industry features and marketing practices described above often is to allow brand manufacturers to gain and maintain monopoly power.

36. Congress sought to ameliorate this "disconnect," and to restore some of the normal competitive pressures to the pharmaceutical marketplace, by authorizing the manufacture and sale of generic pharmaceuticals under the Hatch-Waxman Act. When a pharmacist receives a prescription for a branded pharmaceutical product, and a generic version of that product is available, state laws permit (or in some cases require) the pharmacist to dispense the generic product in lieu of the branded product. In this way, the importance of price is reintroduced to the product selection decision at the pharmacy counter, and the pharmaceutical marketplace "disconnect" is ameliorated. When a generic product is introduced and is not prevented from competing unfettered, branded pharmaceutical manufacturers are no longer able to exploit these unique features of the pharmaceutical marketplace, their monopoly power dissipates, and some of the normal competitive pressures are restored.

37. If Allergan (f/k/a Actavis) and its wholly-owned subsidiary Warner Chilcott had not unlawfully impaired generic competition with respect to the Asacol franchise products, purchasers like Plaintiff and members of the Classes would have saved hundreds of millions of dollars per year on their purchases of those products. The Defendants' anticompetitive scheme purposely impaired and delayed generic competition to those franchise products.

B. The Economic Benefits of Generic Drugs

38. Generic versions of brand drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand counterparts. The only material difference between generic drugs and brand drugs is their price: generic drugs are usually at least 10% less expensive than their brand drug counterparts when there is a single generic drug competitor. The discount typically increases to 50% to 80% (or more) when there are multiple generic drug competitors in the market for a given brand drug.

39. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The FTC estimates that about one year after market entry, generic drugs take more than 90% of the brand drug's unit sales at an 85% discount off the brand price. As a result, competition from generic drugs is viewed by brand manufacturers, such as the Scheme Defendants, as a grave threat to their bottom lines.

40. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute the generic drug when presented with a prescription for the brand drug. Since passage of the Hatch-Waxman Act, every state has adopted substitution laws requiring or permitting pharmacies to substitute generic drug equivalents for branded drug prescriptions (unless the prescribing physician specifically orders otherwise by writing "dispense as written" or similar language on the prescription).

41. Until the generic version of a brand drug enters the market, however, there is no bioequivalent generic drug to substitute for, and compete with, the brand drug, and, therefore, the brand manufacturer can continue to profitably charge supracompetitive prices. Brand drug manufacturers, which are well aware of the rapid erosion of brand drug sales by generic drugs, have a strong incentive to impair generic competition, including through tactics that are unlawful.

C. The Regulatory Structure for Approval of Generic Drugs

42. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), brand drug manufacturers must obtain FDA approval to sell a new drug product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data

concerning safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a) and (b).

43. When the FDA approves a manufacturer's NDA, the manufacturer may list in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") any patents that meet certain criteria, discussed in further detail below, and that the manufacturer could reasonably assert against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the patents' expiration. For patents issued after the FDA approves the NDA, the brand manufacturer may list them in the Orange Book within thirty days of their issuance. 21 U.S.C. § 355(b)(1) and (c)(2).

44. The FDA relies completely on a brand manufacturer's truthfulness about patent validity and applicability because the FDA does not have the resources or authority to verify the manufacturer's representations. In listing patents and patent information in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Act

45. The Hatch-Waxman Act, enacted in 1984, simplified the regulatory hurdles for prospective generic drug manufacturers by eliminating the need to file lengthy and costly NDAs. A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in a brand manufacturer's original NDA, but must further show that the generic drug (i) contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and (ii) is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and

bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns an "AB" rating to generic drugs that are therapeutically equivalent to their brand-name counterparts.

46. The FDCA and Hatch-Waxman Act operate on the presumption that bioequivalent drugs containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence means that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as its brand counterpart.

47. Through the Hatch-Waxman Act, Congress sought to expedite the entry of generic drugs into the marketplace, thereby reducing healthcare expenses nationwide. Congress also wanted to protect pharmaceutical manufacturers' incentives to create new and innovative products.

48. The Hatch-Waxman Act achieved both goals by advancing substantially the rate of generic product launches and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Act, only 35% of the top-selling brand drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, annual prescription drug revenue for brand and generic drugs totaled $21.6 billion; by 2009 total annual prescription drug revenue had soared to $300 billion, with generic drugs accounting for 75% of prescriptions.

49. In addition to the Hatch-Waxman Act, state generic-substitution laws in all fifty states also strongly encourage the use of generic drugs. These laws allow, and sometimes require, pharmacists to fill prescriptions for brand drugs with cheaper generic equivalents, unless

the prescribing doctor directs otherwise. State substitution laws are specifically designed to ameliorate the disconnect in the United States healthcare industry between the doctors who choose but do not pay, and the individuals and institutions who pay but do not choose.

2. Paragraph IV Certifications

50. If the NDA holder has submitted patent information describing a listed patent as claiming a relevant drug substance or drug product, an ANDA applicant must certify that the generic drug will not infringe those patents. Under the Hatch-Waxman Act, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic drug manufacturer's proposed product (a "Paragraph IV certification").

51. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand drug manufacturer initiates a patent infringement action against the generic drug manufacturer within forty-five days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic drug manufacturer's ANDA.

52. As an incentive to generic manufacturers to seek approval of generic alternatives to brand drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV

certification typically receives a period of protection from competition from other generic versions of the drug approved through the ANDA process. For Paragraph IV certifications made after December 8, 2003, the first generic manufacturer applicant receives 180 days of market exclusivity. This means the first approved generic drug is the only available ANDA-based generic drug for at least six months.

53. Brand drug manufacturers can "game the system" by suing any generic drug manufacturer filing an ANDA with a Paragraph IV certification (even if the competitor's product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. Brand drug manufacturers often sue generic drug manufacturers under Hatch-Waxman simply to delay generic drug competition—as opposed to enforcing a valid patent that is actually infringed by the generic drug—as demonstrated by the fact that generic manufacturers have prevailed in Paragraph IV litigation in cases involving 73% of the drug products studied.

D. Pharmaceutical Manufacturers Game the Regulatory Structure in Order to Prevent Competition

54. Brand manufacturers have developed several ways to game the system – to abuse the regulatory structure – in order to prevent or delay generic entry.

1. Product Hopping

55. One way that brand manufacturers impair generic competition is by preventing the generic from being AB-rated to the brand drug and thereby impairing generic substitution. The AB-rating requirement for generic drugs is designed to ensure therapeutic equivalence to the reference product. It is concerned only with safety and efficacy and not with effects on competition.

56. FDA regulations permit brand manufacturers to seek FDA approval to modify the dosage form and strength of their existing products. An unscrupulous brand manufacturer that anticipates the onset of generic competition to its drug can modify the dosage form, strength, or some other characteristic of its product from, say, A to A_1, for the purpose of preventing the anticipated generic product from being A-B rated to the new brand product. Before the generic manufacturer receives FDA approval for the generic version of A and enters the market, the brand manufacturer can get approval for A_1 and cannibalize the sales of A – use its massive sales force to get doctors to switch their prescriptions from A to A_1. Thus, before the generic of A enters the market the brand manufacturer will have: (a) ensured that the generic product cannot be A-B rated to, and substitutable for, A_1; and (b) switched the prescription base from A to A_1. Consequently, when the generic finally gets FDA approval to enter the market, it will garner few or no sales because it is not substitutable for the new brand product to which the prescription base has been switched.

57. The timing of the product hop is critical. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. For example, one brand manufacturer estimated that it would make ten times more sales of its branded follow-on product if it beat generic versions of the original product onto the market. In a detailed inquiry into the pharmaceutical industry, the European Commission concluded that "it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity." European Commission, Final Report, p. 356 (8 July 2009), available at http://www.europa-nu.nl/id/vi6wcj7amsx3/pharmaceutical_sector_inquiry_fianl?start-006-00c=10. Industry analysts

in the United States have reached the same conclusion, warning brand manufacturers that it is essential that they switch patients to the new formulation before the generic enters.

58. It is equally well known that, after a product hop, doctors are unlikely to prescribe the original product – in this case, Asacol (400mg). Having switched their prescribing habits from the original to the reformulated product—and having switched specific patients' medications from the original to a reformulated product—most doctors will not switch their prescribing habits or their patients back to the original product after the generic is available. And pharmacists are unable to effect the switch through the efficient mechanism of automatic substitution because the dosage form and/or dosage amount is different. Thus, in most instances, the generic's opportunity to compete for those sales is gone forever.

59. Brand manufactures know that, if they successfully cannibalize the original product's sales before the generics enter the market, the generics are not likely to *ever* come to market. Automatic substitution at the pharmacy counter is a generic product's only commercially viable means of competing. Once the brand's patents are no longer effective, *no one* – neither the brand manufacturer nor any generic manufacturers – can profitably market the product on a basis other than price. Costs incurred to encourage a doctor to write a prescription for one's product would be squandered because the pharmacist can fill the prescription with a competitor's A/B-rated product. And this is a good thing. If a manufacturer could profitably market the product to doctors on a basis other than price, this would merely replicate the price-disconnect failure in these markets. The price disconnect is the problem, and A/B-rated substitution at the pharmacy counter is the cure. The generic-substitution regime is *designed* to render unprofitable active marketing of the product to doctors.

2. Falsely Listing and Describing Patents in the Orange Book

60. The Hatch-Waxman Act and FDA regulations require a sponsor of an NDA to submit to FDA a list of patents claiming the approved drug substance or drug product, or claiming an approved method of using the drug product described in the NDA. Specifically, section 505(b)(l) of the Act requires NDA applicants to file as part of the NDA "the patent number and the expiration date of any patent which *claims the drug* for which the applicant submitted the application or which *claims a method of using such drug* and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(l) (emphasis added).

61. Similarly, the relevant regulations provide that the manufacturer shall list in the Orange Book only a patent "that *claims the drug or a method of using the drug* that is the subject of the new drug application or amendment or supplement to it," and further provide that "[f]or purposes of this part, such patents consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents….." 21 C.F.R. 314.53(b)(1). The regulations define a "drug product" as "a finished dosage form, for example, *tablet, capsule, or solution, that contains a drug substance,* generally, but not necessarily, in association with one or more other ingredients." 21 C.F.R. 314.3(b) (emphasis added).

62. Brand manufacturers can game the system by listing in the Orange Book patents that do not in fact claim the drug product. Such regulatory gaming is effective in impairing competition because in listing patents and patent information in the Orange Book the FDA merely performs a ministerial act. The FDA relies completely on a brand manufacturer's truthfulness about the nature of the patent because the FDA does not have the resources or authority to verify the manufacturer's patents and patent information for accuracy or trustworthiness. *See, e.g., Abbreviated New Drug Application Regulations: Patent and*

Exclusivity Provisions, 59 Fed. Reg. 50338, 50343-45 (Oct. 3, 1994); FDA/CDER response to citizen petition re: Actos and Acto*plus* met, Docket No. FDA-2009-P-0411-0010 (Mar. 15, 2010), at 9.

63. Any person may dispute the accuracy of patent information listed in the Orange Book by notifying the FDA in writing (21 CFR § 314.53(f)). But in response the FDA simply asks the brand manufacturer to verify the information it provided originally and makes no changes in the Orange Book "[u]nless the [brand manufacturer] withdraws or amends" the listing. Again, the FDA does not attempt to verify the accuracy of the patent information that brand manufacturers supply. It simply publishes the supplied information in the Orange Book.

64. As noted above, important regulatory and competitive consequences flow from the brand manufacturer's listing a patent in the Orange Book as claiming the drug product. If the brand manufacturer lists a patent as claiming the drug product, an ANDA applicant desiring to market its generic product before the patent expires must file a Paragraph IV certification, certifying that the patent is invalid, unenforceable, or would not be infringed by the generic product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). The patentee and/or NDA holder then has the opportunity to obtain an automatic 30-month stay on generic competition by filing a patent infringement lawsuit against the ANDA applicant within 45 days of receiving the Paragraph IV certification. Simply by suing on an Orange-Book-listed patent within 45 days, the brand manufacturer *automatically* prevents the FDA, *without regard to the merits of the lawsuit*, from granting final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic drug manufacturer's ANDA.

3. Exclusion Payments

65. Another way that brand manufacturers game the system to anticompetitive effect is by paying generic manufacturers to delay entering the market. In connection with the resolution of patent litigation arising out of Paragraph IV certifications, brand manufacturers pay off generic competitors in exchange for their delaying entry into the market. These agreements not to compete are sometimes known as "exclusion payment agreements," or "pay-for-delay agreements," or "reverse payment agreements." Brand and generic manufacturers execute exclusion payment agreements as purported settlements of patent infringement lawsuits that brand manufacturers file against generic manufacturers.

66. In a typical exclusion payment agreement, the brand manufacturer pays a generic manufacturer to delay or abandon market entry, and to abandon the challenge to the brand manufacturer's patents. The brand manufacturer preserves its monopoly by effectively paying some of the monopoly profits to the generic manufacturer, which in turn agrees to delay marketing its product.

67. In the 1990s these agreements sometimes took the form of cash payments from the brand manufacturer to the generic competitor. As a result of regulatory scrutiny, congressional investigations, and class action lawsuits, brand manufacturers and generic competitors have entered into increasingly elaborate agreements in an attempt to mask the fundamentally anticompetitive character of the agreements.

68. In an increasing number of instances, brand manufacturers disguise an exclusion payment to a first-filing generic manufacturer by including in the agreement a No-Authorized-Generic Clause ("No-AG Clause"). A No-AG Clause provides that the brand manufacturer will not market an "authorized generic" version of the brand drug in competition with the first-filer. An authorized generic is the brand drug, manufactured just like the brand product, but sold as a

generic product under the same approval as the brand product's original NDA. A brand manufacturer does not need to file an ANDA, or obtain any additional FDA approvals, to market a chemically identical generic version of a drug for which it has received approval through the NDA process.

69. Importantly, the 180-day period of market exclusivity to which a first-filing ANDA applicant (the "first-filer") may be entitled under the Hatch-Waxman Act does not prevent the brand manufacturer from marketing an authorized generic version of the drug during the first-filer's 180-day "exclusivity." The 180-day marketing period is "exclusive" only as against other ANDA-based products, not as against the brand manufacturer's NDA-based product.

70. For the brand manufacturer, launching an authorized generic during the 180-day period provides a low cost, low risk means of retaining some of the sales and revenue that it would otherwise lose to the generic first-filer. Absent a No-AG Clause, it almost always makes economic sense for a brand manufacturer to market an authorized generic version of a big-selling drug during the first-filer generic manufacturer's 180-day "exclusivity" period. One study notes that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'" Hassett, K. A. and R. J. Shapiro, "The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals," Sonecon, May 2007, p. 3. A study analyzing three examples of authorized generics found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand." Berndt, E., R. Mortimer, A. Bhattacharjya, A. Parece

and E. Tuttle, "Authorized Generic Drugs, Price Competition, and Consumers' Welfare," Health Affairs, v. 26, n. 3, May/June 2007, p. 796

71. For the generic manufacturer holding a 180-day exclusivity, the brand manufacturer's marketing of an authorized generic has a substantially negative effect on revenue and profits. In the absence of competition from other generics, during the 180-day exclusivity period a first-filer generic manufacturer generally makes about 80% of all of the profits that it will ever make on the product. Competition from another generic during that period typically cuts the first-filer's revenues by more than half, as the competing generic takes a substantial volume of the unit sales (typically about half of such sales) and drives prices lower. Freedom from an authorized generic during the initial 180-day period is thus exceedingly valuable to the generic first-filer, more than doubling its revenues and profits.

72. To prevent this substantial loss of revenue and profit from competition from an authorized generic, a generic first-filer may be willing to delay its entry into the market in return for a No-AG Clause. A brand manufacturer's payment to the first-filer generic in the form of a No-AG Clause is economically equivalent to a cash payment because the clause effectively doubles (or more) the first-filer's revenues and profits.

73. The additional monopoly profits that the brand manufacturer gains by delaying the onset of generic competition more than makes up for the profits that it forgoes by not competing with an authorized generic. The brand manufacturer gains by delaying the onset of generic competition. The generic first-filer gains by ensuring the absence of generic competition for at least the first 180 days of marketing. And drug purchasers lose twice – first by the delay in the onset of generic competition, and then by the absence of authorized-generic competition once generic entry finally occurs.

V. WARNER CHILCOTT AND ALLERGAN'S ANTICOMPETITIVE SCHEME TO IMPAIR GENERIC COMPETITION

A. Ulcerative Colitis and Asacol

74. Ulcerative colitis is a chronic debilitating inflammatory bowel disorder that typically causes bloody diarrhea, rectal urgency, tenesmus, and abdominal cramping. The disorder may also affect the skin, eyes, joints or livers of ulcerative colitis sufferers. The condition is present in 238 out of 100,000 people in the United States. If inflammation persists or is left untreated, ulcerative colitis increases the risk of colorectal cancers.

75. Ulcerative colitis is a cyclical disorder, meaning patients are often without symptoms for periods of time but will then develop another ulcer (i.e. have another "flare"). This disease cycle requires two modes of treatment, one for acute symptoms and another for long-term maintenance of remission.

76. The most common treatment for ulcerative colitis is a class of drugs containing the active ingredient mesalamine. Mesalamine drugs operate topically, meaning they reduce inflammation upon contact with the inflamed portion of the colon, not from systematic changes to the body. Mesalamine formulations primarily differ as to where the active ingredient is released along the gastrointestinal tract. If the mesalamine is released too early—in the stomach or small intestine—then the active ingredient may not reach the colon and will not provide relief. If the mesalamine is released too late, much of the ingredient will pass through the body, again offering no relief.

77. Proctor & Gamble received approval to market a delayed-release oral tablet containing 400 mg of mesalamine to treat mild to moderately active ulcerative colitis, sold under

the brand name Asacol, on January 31, 1992. On August 19, 1997, the drug received an additional FDA indication for the maintenance of the remission of ulcerative colitis.

78. Asacol (400mg) was a specific controlled-release mesalamine formulation that was designed to dissolve in the intestines, not in the stomach. The enteric coating ("enteric" meaning "of the small intestine") allows Asacol (400mg) tablets to pass through the stomach largely intact and then release active mesalamine directly into the affected areas of the colon.

79. Proctor & Gamble listed two patents in the FDA's Orange Book for Asacol (400mg), U.S. Patent No. 5,541,170 ("the '170 patent") and 5,541,171 ("the '171 patent"). Both patents expired July 30, 2013.

80. By 2004, Asacol (400mg) was one of Proctor & Gamble's best selling prescription products. The drug became one of the top 100 selling pharmaceuticals in the United States that year, with sales of approximately $322 million.

B. Cannibalizing Asacol (400mg) Sales to Asacol HD

81. As with many patent-protected drug products, Proctor & Gamble knew that, if it did nothing, its enormous Asacol (400mg) profits would end when the applicable patents expired on July 30, 2013. On that date, competitors would begin to sell generic Asacol (400mg) at lower prices and would quickly garner most sales, as intended by the Hatch-Waxman Act and state generic-substitution laws. Proctor & Gamble therefore developed a strategy to retain sales and extend the Asacol monopoly beyond the period provided by the '170 and '171 patents.

82. On or about October 24, 2004, Proctor & Gamble submitted NDA No. 21-830 for an 800 mg, long-acting mesalamine tablet that was later marketed as "Asacol HD." The FDA approved Asacol HD on May 29, 2008.

83. The FDA approved Asacol HD exclusively for the treatment of *moderately* active ulcerative colitis. Unlike Asacol (400mg), this new drug was not approved for the treatment of the two other conditions—*mildly* active ulcerative colitis or *maintenance of remission* of ulcerative colitis.

84. Proctor & Gamble listed two new patents in the Orange Book for Asacol HD, U.S. Patent No. 6,893,662 and 8,580,302. Both of these will expire November 15, 2021.

85. Critical to Proctor & Gamble's maintenance of the Asacol franchise, pharmacists could not automatically substitute prescriptions for Asacol HD with generic Asacol (400mg) because Asacol HD was a different dosage strength (800mg) than Asacol (400mg). As a result, Proctor & Gamble knew that most, if not all, patients who were prescribed Asacol HD would be able to fill their prescriptions only with Asacol HD at brand prices, long after a generic version of Asacol (400mg) came to market in July 2013.

86. In the summer of 2009, Proctor & Gamble announced that it would sell its brand pharmaceutical division to Warner Chilcott. Warner Chilcott acquired Proctor & Gamble's interests in Asacol (400mg) and Asacol HD on October 30, 2009.

87. When Warner Chilcott acquired Asacol (400mg), the drug was an immensely successful product. In 2009, it was the 75th top-selling prescription drug in the United States, with annual sales of $490 million.

88. At that time, the conventional wisdom was that Asacol (400mg) had less than four years of immense profitability remaining before July 2013, when the '170 and '171 patents would expire, and generic competition would begin. But one of Warner Chilcott's principal purposes in acquiring Proctor & Gamble's pharmaceutical division was to acquire Asacol

(400mg) because Warner Chilcott thought it could implement an unlawful scheme to prevent generic Asacol (400mg) from ever coming to market.

89. Beginning shortly after the 2009 acquisition, Warner Chilcott exerted extraordinary efforts, including independently unlawful actions such as off-label marketing and paying kickbacks to doctors, to switch patients from Asacol (400mg) to Asacol HD. Warner Chilcott knew that if it switched the prescription base to Asacol HD before July 2013, those prescriptions would not be switched back to Asacol (400mg) even if generic versions of that product entered the market at that time.

90. Warner Chilcott knew that this strategy, which depended on patients staying on a particular formulation for extended periods, would be particularly effective with Asacol patients. Ulcerative colitis is a lifelong condition, and ulcerative colitis patients like to stay on a single drug once they find one that works. Patients prefer not to risk unnecessary symptoms by switching drugs. Warner Chilcott CEO Roger Boissonneault specifically recognized this feature of the Asacol marketplace:

> [W]hen someone is put on Asacol for their ulcerative colitis, it is likely that they put on the product 20 to 30 years old [*sic*], and they are probably going to be taking that product for the rest of their lives, because it prevents the disease, and every once in a while they get a flare, and then you have to use corticosteroids to bring it back, and they certainly become – I mean it is indeed a great product but it is a product that is used in the long term.

Warner Chilcott CEO Discusses 2012 Guidance (Transcript), Jan. 27, 2012, *available at* http://seekingalpha.com/article/322720-warner-chilcott-ceo-discusses-2012-guidance-transcript.

91. But Asacol (400mg) and Asacol HD were not approved to treat the same conditions, so Warner Chilcott could not *lawfully* market Asacol HD to most Asacol (400mg) patients. Asacol (400mg) was approved to treat three different conditions: *mildly* active ulcerative colitis; *moderately* active ulcerative colitis; and, the *maintenance of remission* of

ulcerative colitis. Asacol HD was approved only to treat *moderately* active ulcerative colitis. Only Asacol (400mg) was approved for long-term maintenance of remission therapy, which accounts for the bulk of Asacol (400mg) prescriptions, while Asacol HD was approved only for the short-term treatment of severe flares (an indication it shares with Asacol (400mg)).

92. Proctor & Gamble had initially sought FDA approval for Asacol HD as a superior treatment for mildly and moderately active ulcerative colitis as compared to Asacol (400mg). After poor clinical results, Proctor & Gamble reduced its proposed indications for Asacol HD to treat only moderately active ulcerative colitis. Proctor & Gamble also changed its goal from demonstrating "superiority" over the original formulation to demonstrating "noninferiority" to the original product. Proctor & Gamble never attempted to get Asacol HD approved for the maintenance of remission of ulcerative colitis.

93. After purchasing the Asacol franchise, Warner Chilcott began unlawfully promoting Asacol HD to treat mildly active ulcerative colitis and maintenance of remission therapy, which made up the bulk of Asacol (400mg) prescriptions. Despite the legal prohibitions, Warner Chilcott began an aggressive marketing campaign to switch patients from Asacol (400mg) to Asacol HD. This was Warner Chilcott's top priority throughout 2010 and 2011. CEO Boissonneault, responding to a question about the ongoing patient shift, revealed his plan to entirely disregard the two drugs' different indications:

> I think we lost a little bit of focus in the fact that convincing clinicians that you shouldn't use the 400 you should be using the HD. The issue is the reason that you use Asacol is not because it's 400 milligrams or 800 milligrams. The fact is that it works quickly, it's well tolerated and you can virtually take this for a long period of time.

Warner Chilcott PLC's CEO Discusses Q2 2011 Results – Earnings Conference Call (Transcript), Aug. 5, 2011, *available at* http://seekingalpha.com/article/285263-warner-chilcott-plcs-ceo-discusses-q2-2011-results-earnings-conference-call.

94. Later in the same conference call, Boissonneault described how Warner Chilcott cannibalized the Asacol (400mg) sales: "If you go back and look at it and we – what happened was we took some [dermatology sales representatives] and we took some [gastrointestinal sales representatives] and put them together it was like a simplistic execution: Just move the 400 milligram to the HD." *Id*.

95. Warner Chilcott's effort to switch patients to Asacol HD has already come under legal scrutiny. In April 2016, Warner Chilcott pled guilty to felony healthcare fraud (18 U.S.C. § 1347) for unlawfully paying kickbacks to prescribers of Asacol and Asacol HD (among other drugs) between October 2009 and September 2013. Warner Chilcott agreed to pay a criminal fine of $20.74 million, forfeit $2 million in assets, and settle civil allegations for $102.06 million.

96. This plea and settlement arose from a March 2011 *qui tam* action in which two former Warner Chilcott employees (who were former Proctor & Gamble employees) accused the company, in part, of conducting a widespread off-label marketing campaign to cannibalize Asacol (400mg) sales in favor of Asacol HD in violation of federal law. Plaintiffs' Third Amended Complaint at 3-4, *United States ex rel. Alexander v. Warner Chilcott PLC, et al*., No. 11-cv-10545 (D. Mass Aug. 8, 2013), ECF No. 45.

97. The *qui tam* plaintiffs alleged that, as part of its effort to cannibalize the Asacol (400mg) sales before the '170 and '171 patents expired, Warner Chilcott deliberately misrepresented the clinical evidence supporting Asacol HD. As extensively alleged in the *qui tam* complaint, it was Warner Chilcott's policy to convince doctors to prescribe Asacol HD for

all ulcerative colitis patients, not just those with moderately active ulcerative colitis. *See id*. at 151-158.

98. As part of the felony plea, Warner Chilcott admitted that its sales representatives compensated doctors who prescribed high amounts of Warner Chilcott products with so-called "Medical Education Programs," which were in reality high-priced dinners that contained no medical education, and "Speaker Roundtables," which were pretexts to compensate high prescribing physicians with "speaking fees." Warner Chilcott also agreed that it had instructed its sales representatives to submit fraudulent prior authorizations, which allowed physicians to prescribe Warner Chilcott products despite insurers' formulary restrictions.

99. Warner Chilcott also acknowledged that its overall corporate culture was hyper-aggressive and reckless during this period. As admitted in the Criminal Information to which it pled guilty, Warner Chilcott preferred to hire young, assertive sales representatives (known as "Type A, crazy") with no experience in medical sales and even sought such individuals through "a personality test designed to highlight candidates who were aggressive and not sensitive to rules" who could then be counted on to uphold the hyper-aggressive "Warner Chilcott way." Warner Chilcott executives referred to those who would not adhere to this culture, many of whom were legacy Proctor & Gamble employees, as "creampuffs."

100. In addition to charges against Warner Chilcott, in October 2015 the President of its Pharmaceuticals Division from 2009 to 2011, Carl Reichel, was personally indicted for Conspiracy to Violate Anti-Kickback Statutes (18 U.S.C. § 371). The indictment alleges that Warner Chilcott engaged in hyper-aggressive and fraudulent marketing practices to promote its products, including Asacol HD.

101. Warner Chilcott's cannibalizing of Asacol HD before expiration of the '170 and '171 patents was remarkably successful, especially given that Asacol HD is not approved for maintenance therapy—which accounts for the bulk of ulcerative colitis prescriptions. In 2010, Asacol HD made up 9% of Warner Chilcott's total Asacol franchise sales (which is an indication of the true size of the "moderately active" segment of the market since it predated the aggressive off-label marketing efforts that led to Warner Chilcott's pleading guilty to criminal conduct). By 2012, as a direct result of Warner Chilcott's sustained off-label marketing campaign and its admitted criminal conduct, Asacol HD sales ballooned to 28% of Warner Chilcott's Asacol franchise.

C. Cannibalizing Asacol (400mg) Sales to Delzicol

102. Even after engaging in its aggressive scheme to switch as many patients as possible to Asacol HD, Warner Chilcott still expected to lose the vast majority of its Asacol franchise once its two original patents expired on July 30, 2013, because sales of Asacol (400mg) still constituted 72% of the overall franchise in 2012. Even if Warner Chilcott switched 50% of Asacol (400mg) patients to Asacol HD by the summer of 2013, it would still lose hundreds of millions of dollars to generic competition.

103. On July 31, 2012, Warner Chilcott submitted NDA No. 204412 for a mesalamine product, which it later sold under the brand name Delzicol. The FDA approved Delzicol for sale six months later on February 1, 2013.

104. Warner Chilcott touted Delzicol as a significant improvement to investors and the general public. During an investor call in early 2013, Warner Chilcott's CEO bragged about its ability to innovate: "The approval of Delzicol, our new 400-milligram delayed-release mesalamine product, provides you with tangible evidence of our ability to successfully develop

improved versions of our key product." Warner Chilcott Management Discusses Q4 2012 Results – Earnings Call Transcript, Feb. 22, 2013, *available at* http://seekingalpha.com/article/1216961-warner-chilcott-management-discusses-q4-2012-results-earnings-call-transcript.

105. In reality, the FDA approved Delzicol based on its bioequivalence to Asacol (400mg). Warner Chilcott established bioequivalence by submitting a comparative pharmacokinetic study and comparative dissolution studies showing that Delzicol would act similarly to Asacol (400mg) in the human body. Warner Chilcott did not conduct additional clinical efficacy trials or additional safety trials in support of its Delzicol application.

106. Warner Chilcott identified only two differences between Asacol (400mg) and Delzicol in its FDA submissions: (1) Delzicol consists of a cellulose capsule inside of which is placed an Asacol (400mg) tablet; and (2) rather than using dibutyl phthalate ("DBP") as an inactive coating ingredient, as Asacol (400mg) did, Delzicol instead uses dibutyl sebacate ("DBS").

107. If Warner Chilcott's had merely used DBS instead of DBP, generic Asacol (400mg) would have been AB-rated to, and substitutable for, prescriptions written for Delzicol. Differences in excipients and other inactive ingredients such as DBS and DBP generally do not affect FDA's evaluation of therapeutic equivalence.

108. Warner Chilcott therefore included the cellulose capsule in order to destroy generic substitutability (and to provide an improper regulatory predicate for improper patent litigation, discussed in detail below). Unlike a change in inactive ingredients such as DBS and DBP, switching the product from a tablet to a capsule *does* prevent an AB-rating and *does*

prevent generic Asacol (400mg) from being substitutable for the new Delzicol under state pharmacy laws.

109. Warner Chilcott offered no medical justification for switching to a capsule form in its NDA for Delzicol. Indeed, according to the NDA for Delzicol, "no new safety and or efficacy trials were conducted by the Applicant using the proposed capsule product."

110. Using the empty capsule to cover the 400mg tablet destroyed generic substitutability, was entirely unnecessary, did not provide any therapeutic benefits to patients, and was actually harmful to patients due to its size. The switch made by Warner Chillcott from a tablet form to a capsule form (1) made no improvement of any kind in the product; (2) made the product more difficult to use and harmful to the consumers (*i.e.*, patients); and (3) was made solely to impair competition from an AB-rated generic version of the drug. Warner Chilcott marketed the 400mg tablet in the capsule solely in order to further its monopolization scheme:

a. *First*, the FDA approved Delzicol exclusively on the basis of bioequivalence to Asacol (400mg). This eliminates the possibility that the Delzicol capsule made the overall product medically superior to Asacol (400mg).

b. *Second*, the capsule around Delzicol quickly dissolves in stomach acid. Thus, the cellulose capsule provides no protection to the enteric-coated Asacol tablet underneath. Enteric coatings are designed to protect active drug ingredients from stomach acid so these ingredients can be released in the gastrointestinal tract. Cole et al., *Enteric Coated HPMC Capsules Designed to Achieve Intestinal Targeting*, 231 INT. J. OF PHARMACEUTICS 83, 83 (2002). Taken together, this means that the capsule surrounding the Delzicol tablet is entirely unnecessary because the enteric coating on the Asacol (400mg) tablet prevents the mesalamine from releasing in the stomach.

c. *Third*, Warner Chicott's stated justification at the time of the change, the need to replace the inactive ingredient DBP, was a mere pretext. In truth, a switch from DBP to DBS did not require using a capsule. Absent the anticompetitive product hopping scheme, Warner Chilcott still would have switched from DBP to DBS (as it was getting pressure from the FDA to do); it just would not have encased the Asacol (400mg) tablet in a large, costly and unnecessary capsule. Indeed, a Warner Chilcott or Allergan

> foreign subsidiary successfully removed DBP from its identical mesalamine product in the United Kingdom without adding a cellulose capsule. Upon information and belief, the company did not introduce a capsule product in the United Kingdom, as it did in the United States with Delzicol, because this unnecessary feature would not allow the company to game the UK regulatory system.

111. Further, the unnecessary Delzicol capsule made the product more difficult to swallow than the original formulation for many patients. In April 2014, the FDA issued an Addendum Clinical Review that summarized patients' difficulties swallowing Delzicol compared to Asacol (400mg). The FDA referred to 49 instances in which patients had difficulty swallowing Delzicol compared to 18 reported instances in which patients had difficulty swallowing Asacol (400mg) or Asacol HD.

112. Patients' difficulty in swallowing Delzicol capsules prevented the FDA from approving Delzicol for the treatment of ulcerative colitis in those younger than 12-years old. While Warner Chilcott received a pediatric indication for Delzicol for those patients 12 and over based on previous Asacol (400mg) pediatric studies, the FDA did not allow Warner Chilcott to use these same studies to establish safety and efficacy in children under 12 years old because the Delzicol capsule may be too large for this population to swallow. As the FDA indicated, by encapsulating the tablet, the size of the pill swelled by over 50%, growing from 14 mm for the Asacol (400) tablet to 21.7 mm for the Delzicol capsule (although the tablet inside the Delzicol capsule is the same size as the Asacol (400) tablet, as shown in the photograph below).

113. Shortly after Delzicol's release in the spring of 2013, doctors and patients quickly realized that Delzicol is essentially an Asacol (400mg) tablet surrounded by an unnecessary capsule.

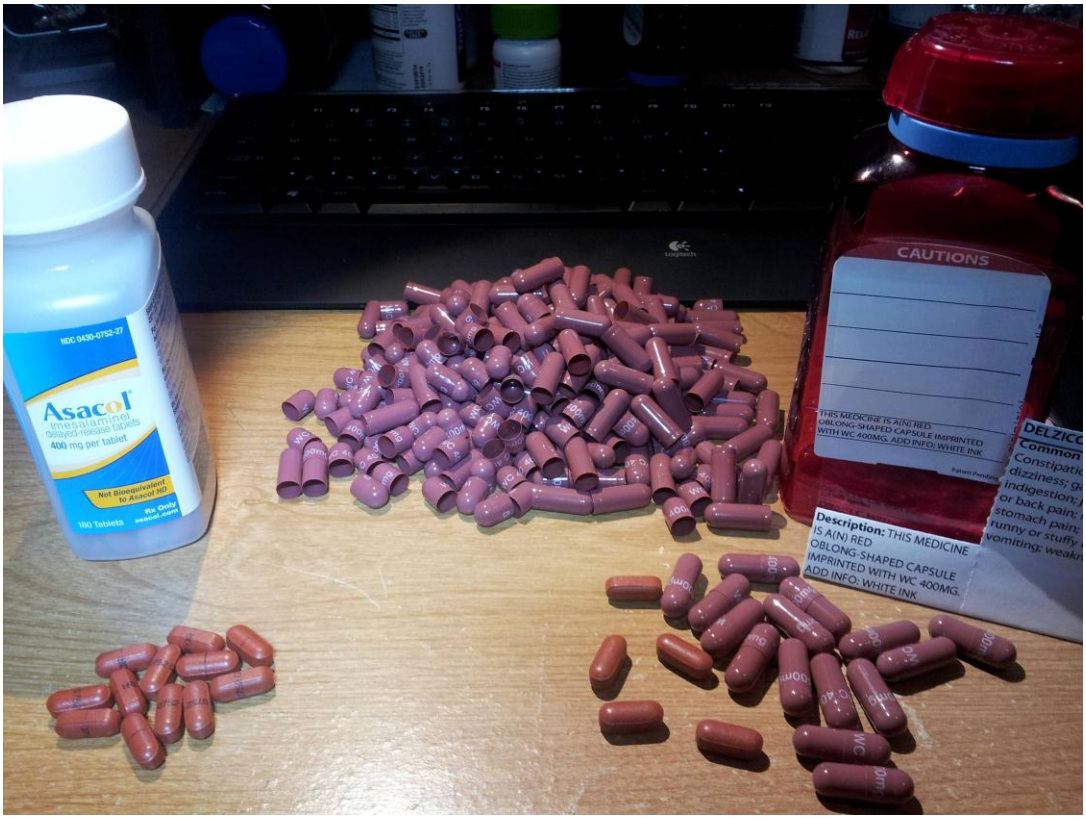
114. An Oregon newspaper, The Bend Bulletin, recognized the extreme similarity between the drugs and posted a video on YouTube.com. The video depicts schoolteacher Erin

Matlock shaking and then opening a Delzicol capsule, only to find a red tablet that appears identical to "what she was taking before" (meaning Asacol (400mg)). Bend Bulletin, *Delzicol: How new is it?*, https://www.youtube.com/watch?v=eNtahEEygHI. *See also, Delzicol Replacing Asacol*, https://www.youtube.com/watch?v=oIUYFg7wGj8.

115. Similarly, an ulcerative colitis patient posted the following picture on www.redditt.com under the headline "Opened a Delzicol 'capsule' today because it sounded pretty rattly [*sic*]. ...why?":

http://www.reddit.com/r/pharmacy/comments/1fuhxm/opened_a_delzicol_capsule_today_because_it/. The picture appears to depict a 400 milligram Delzicol capsule separated into two pieces, a capsule and a tablet. The tablet inside the Delzicol capsule appears to be a solid red Asacol (400mg) tablet, with the absence of the black lettered pill imprint as the only difference.

116. Another ulcerative colitis patient created a thread discussion page entitled "The difference between asacol and delzicol," [*sic*] posting the following photograph:



The difference between asacol and delzicol., http://www.reddit.com/r/ CrohnsDisease/comments/1cbvel/the_difference_between_asacol_and_ delzicol/. The Delzicol tablets on the right appear to be identical to the Asacol (400mg) tablets on the left, except they do not have the pill imprint "0752 DR," which was the imprint on Asacol (400mg) tablets. *See* http://www.drugs.com/imprints/0752-dr-18756.html.

117. Warner Chilcott attempted to justify this deception under the pretext that it created Delzicol due to safety concerns over DBP, an inactive ingredient in the enteric coating of both Asacol (400mg) and Asacol HD. In 2009, the FDA requested that Warner Chilcott reformulate Asacol (400mg) using a plasticizer other than DBP. As noted above, however, Warner Chilcott's merely changing the inactive ingredient from DBP to DBS would not have prevented generic Asacol (400) from being substitutable for Delzicol. The only thing that

prevented substitutability was Warner Chilcott's switching the form of the product from tablets to the bogus capsules.

118. Warner Chilcott asserted that the FDA's safety concerns regarding DBP prompted it to create a new product (Delzicol) with a new NDA and to withdraw Asacol (400mg) from the market. These were lies. The FDA had made clear as early as 1997 that the preferred administrative process for obtaining approval to change inactive ingredients such as DBP was by post-approval supplement to an existing NDA, *not by submission of a new NDA.* See Guidance for Industry, SUPAC-MR: Modified Release Solid Oral Dosage Forms (September 1997). This approval process allows manufacturers to make changes to their approved products *without submitting a new NDA.* Indeed, no pharmacological or manufacturing concern prevented Warner Chilcott from simply substituting DBS for DBP in Asacol (400mg) using the SUPAC process rather than filing a new NDA.

119. Merely changing inactive ingredients through the FDA-recommended SUPAC process, however, would not have been useful to Warner Chilcott in impairing generic competition. The switch from DBP to DBS through the SUPAC process would not have affected the FDA's evaluation of therapeutic equivalence or its approval of ANDAs for generic Asacol (400mg). Branded Asacol (400mg), made with DBS instead of DBP, would have remained on the market. Generic Asacol (400mg) would have been substitutable for the DBP-free branded Asacol (400mg), and the FDA would have approved those ANDAs.

120. As part of its anticompetitive scheme, however, Warner Chilcott rejected the FDA's request to reformulate Asacol (400mg) to remove DBP from it. Instead, Warner Chilcott left DBP in Asacol (400mg) in order to create a pretext for removing Asacol (400mg) from the market. Rather than removing DBP from Asacol (400mg), Warner Chilcott removed Asacol

(400mg) from the market. As described in detail above, Warner Chilcott replaced Asacol (400mg) with Delzicol, which is essentially Asacol (400mg) made with DBS instead of DBP and with the bogus capsule.

121. In short, Warner Chilcott removed DBP from Asacol (400mg), put a bogus capsule around it, got it approved with a new NDA, and called it Delzicol. The bogus capsule made generic Asacol (400mg) non-substitutable. And Warner Chilcott left DBP in branded Asacol (400mg) in order to provide a rationale for removing that product from the market.

122. Orchestrating the removal of Asacol (400mg) from the market was part of Warner Chilcott's anticompetitive scheme. It is well known in the pharmaceutical industry that a brand manufacturer's product hop will be more successful – that it will cannibalize more of the sales of the original product -- if it withdraws the original product from the market. Warner Chilcott thus knew that it could cannibalize the entire market, and thereby significantly impair generic competition, by withdrawing Asacol (400mg) from the market rather than by merely removing DBP from Asacol (400mg) as the FDA had requested.

123. Warner Chilcott's gaming of the regulatory system had another aspect and another intended anticompetitive effect. After switching the Asacol (400mg) prescription base to Delzicol, Warner Chilcott discontinued marketing Asacol (400mg) altogether, with the intended effect of causing the FDA to delist Asacol (400mg) as a Reference Listed Drug ("RLD"). FDA regulations provide that, in these circumstances, the FDA will refuse to approve any ANDA as to which the delisted product was the RLD if, among other things, the FDA determines that marketing of the RLD was discontinued for safety reasons. By refusing to remove DBP from Asacol (400mg) and discontinuing the marketing of it, Warner Chilcott intentionally created serious uncertainty as to whether the FDA would approve any ANDAs seeking approval for

generic Asacol (400mg). Warner Chilcott's purpose was to impair competition from generic Asacol (400mg).

124. Warner Chilcott launched Delzicol in March 2013, before the FDA approved any ANDAs for generic Asacol (400mg). As noted in detail above, it is well known in the industry that, where a brand manufacturer successfully converts the market before the generics enter the market, the generics will make few or no sales.

125. But for the anticompetitive scheme, Warner Chilcott could and would have addressed the safety issue raised by the FDA by reformulating Asacol (400mg) to remove DBP and replace it with DBS; would not have put a bogus capsule around the tablet; and would not have filed a new NDA. But for the anticompetitive scheme, the FDA would have approved this DBP-free tablet version of Asacol (400mg) because: (1) DBS is an FDA-approved plasticizer that did not have the potential for the side effects sometimes caused by DBP; (2) the capsule added no therapeutic benefit to the tablet drug product that it needlessly covered; and (3) FDA guidance specifically recommended making such a change in plasticizer via a post-approval supplement rather than a new NDA.

126. Warner Chilcott's CEO recognized, and celebrated, the anticompetitive effects of the unlawful scheme. Responding to a question during an investor call, Mr. Boissonneault stated:

> I think, Chris, historically, we've seen those sorts of things happen. **Generally, the generic company doesn't even get launched because the reference product will be Delzicol. There won't be any Asacol out there.** We've seen that happen with Doryx when the generic company got the product approved and by that time, the product had moved on to, say, to 150 or different, had moved on to a tablet because there really isn't that much business. . . . . And basically, as **the reference product has changed** and then moved on to either tablet or new dose form, there really isn't much to be substituted there.

Warner Chilcott Management Discusses Q4 2012 Results – Earnings Call Transcript, Feb. 22, 2013, *available at* http://seekingalpha.com/article/1216961-warner-chilcott-management-discusses-q4-2012-results-earnings-call-transcript (emphasis added).

127. In short, Warner Chilcott knew that if it switched the market before generic entry in July 2013, a generic version would likely never come to market. And even if a generic version did come to market, the prescription base would have been completely eliminated, thus depriving the generic of its only cost-efficient means of competing for sales.

128. In fact, Warner Chilcott's unlawful scheme caused each of the potential manufacturers of generic Asacol (400mg) to abandon their ANDAs for that product.

129. But for Warner Chilcott's unlawful scheme, at least one generic version of Asacol (400mg) would have been available to consumers no later than July 31, 2013. At least one manufacturer would have introduced generic Asacol (400mg) shortly after patent expiration:

a. In September 2007, Roxane Laboratories, Inc. ("Roxane") sent Proctor & Gamble a letter giving notice that Roxane had submitted an ANDA to produce generic Asacol (400mg). The ensuing litigation disclosed that Roxane had already made substantial investments in the development of a generic version of Asacol (400mg). In December 2011, pursuant to stipulation and order of dismissal, Roxane informed the court that it no longer intended to pursue a generic version of Asacol (400mg) before patent expiration in July 2013.

b. On or about June 22, 2010 Par Pharmaceutical, Inc. ("Par") and EMET Pharmaceuticals, LLC ("EMET") submitted ANDA No. 200-730 for a 400mg mesalamine delayed-release oral tablet intended to be bioequivalent to Asacol (400mg). In connection with this application, Par sent Warner Chilcott a "Notice of Paragraph IV Certification" letter saying it intended to challenge the validity or applicability of Asacol (400mg)'s existing patents.

c. On or about October 14, 2010, Lupin Limited announced that it had reached an agreement with Warner Chilcott plc and its U.S. subsidiary, Warner Chilcott Company, LLC to settle then outstanding patent litigation regarding two Warner Chilcott products, Loestrin 24 Fe and Femcon Fe. As part of the settlement, Warner Chilcott agreed that it would allow

Lupin to purchase and dispense an authorized generic version of Asacol (400mg) if a generic version of the drug was introduced by a third party in the United States. This term of the settlement evidences Lupin Limited's expectation that a generic version of Asacol (400mg) would be introduced by a third party in subsequent years.

d. On August 9, 2012, Par Pharmaceuticals and EMET Pharmaceuticals announced that they intended to market a generic version of Asacol (400mg) upon patent expiration. Upon information and belief, Par and EMET were not aware that Warner Chilcott intended to eliminate the market for Asacol (400mg) shortly before they could launch their generic version of the product.

e. In September 2011, Zydus Pharmaceuticals USA, Inc. indicated that it had submitted a Paragraph III certification with respect to the patents on original Asacol (400mg). This meant that Zydus agreed to delay its launch of an FDA approved version of Asacol (400mg) until the drug's patents expired in July 2013.

130. Each of these manufacturers was developing and seeking regulatory approval for a generic version of Asacol (400mg). Absent Warner Chilcott's anticompetitive scheme, at least one of these manufacturers, or others, would have introduced a generic Asacol (400mg) immediately after patent expiration in summer 2013. These generic manufacturers were well aware of the anticompetitive effects that a product hop away from Asacol (400mg) would have on their ability to use automatic substitution to compete in a cost-efficient manner, as described above. And since Warner Chilcott had publicly discussed its proposed product hop by February 2013, if not earlier, these generic manufacturers knew by no later than that date that there would be virtually no market left for their generic versions of Asacol (400mg) by the time the patents expired in July 2013.

131. For example, in one product hop that is notorious in the industry (and which preceded the Asacol product hop), before the generics could enter the market the manufacturer of branded TriCor hopped from Formulation #1 of the drug to Formulation #2. A generic manufacturer nevertheless persevered and got FDA approval for a generic version of

Formulation #1, but then garnered less than 5% of the unit sales, with 95% of the units remaining with the reformulated brand Formulation #2 for which the generic product was not substitutable. When the generic manufacturer then filed an ANDA for a generic version of Formulation #2, the brand manufacturer hopped to yet another reformulation, Formulation #3. Informed by its prior experience, the generic manufacturer then abandoned its quest for approval of a generic version of Formulation #2. The generic manufacturers that abandoned their ANDAs here were likewise informed by the TriCor experience and others like it. The unlawful product hop caused them to stop their quest for FDA approval of generic Asacol (400mg).

132. In addition to making generic Asacol (400mg) *non-substitutable*, Warner Chilcott's conduct also created uncertainty as to whether generic Asacol (400mg) was *non-approvable*. As noted above, Warner Chilcott's refusal to remove DBP from Asacol (400mg) and the withdrawal of that product from the market created uncertainty as to whether the FDA would approve ANDAs for which Asacol (400mg) had been the RLD. The intended effect of Warner Chilcott's conduct was to cause the generic manufacturers to abandon their requests that FDA approve their ANDAs for generic Asacol (400mg).

133. As a direct result of Warner Chilcott's anticompetitive conduct, these generic competitors ceased their efforts to obtain FDA approval before July 2013. But for Warner Chilcott's anticompetitive conduct, one or more of these generic competitors would not have abandoned their efforts to obtain FDA approval of their generic versions of Asacol (400mg), and would have succeeded in obtaining such approval and entering the market by July 31, 2013.

D. Warner Chilcott's Conduct Was Intended To, And Did, Harm Competition

134. As clearly intended, Warner Chilcott's tactics succeeding in excluding would-be generic competitors from their only practical means of distributing their products – by using state substitution laws.

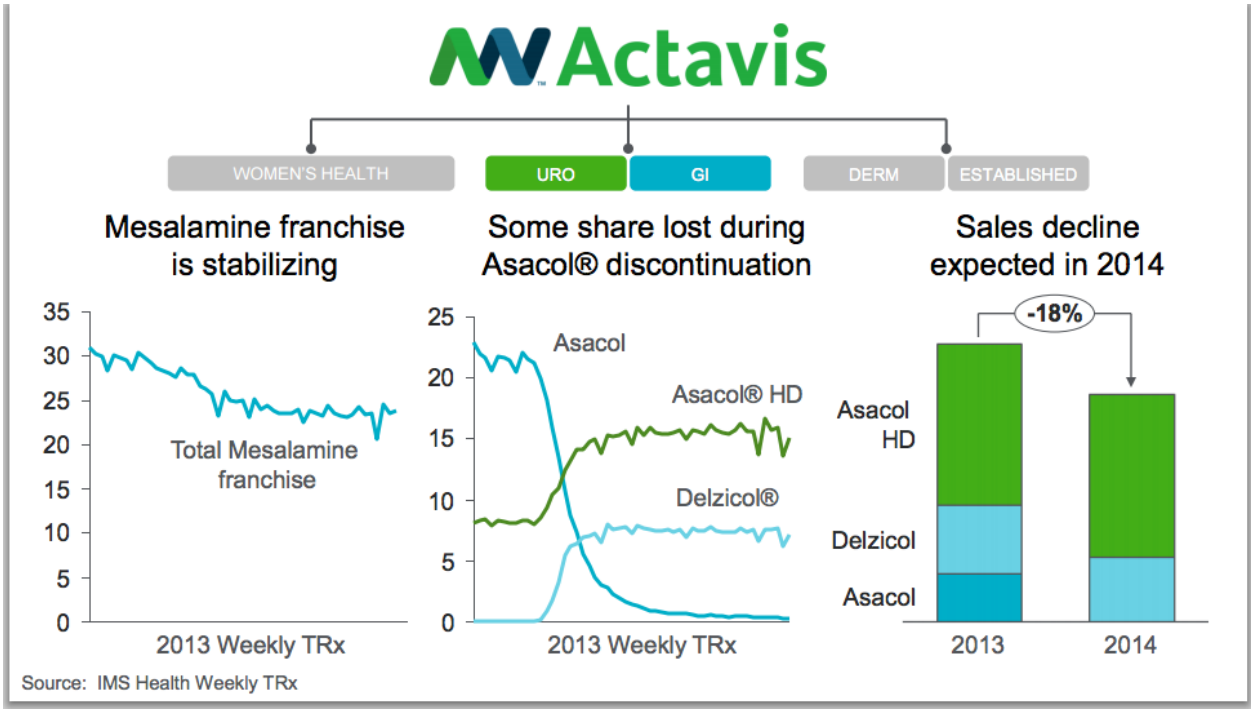
135. Warner Chilcott's exclusionary motive is illustrated by its willingness to sacrifice profits as part of its anticompetitive scheme. Its decisions to incur the extra costs (and suffer the revenue losses) associated with the change in Asacol dosage form from Asacol (400mg) tablets to Asacol HD tablets and Delzicol capsules were economically rational only because those changes had the exclusionary effect of impairing generic competition. But for the impact on generic competition, Warner Chilcott would not have invested the resources necessary to reformulate and cannibalize Asacol (400mg) tablets, because doing so would have been economically irrational.

136. In communications with its shareholders, Warner Chilcott stated that it was losing sales as a result of the unlawful product hop:

> Net sales of ASACOL were $140 million in the quarter ended June 30, 2013, a decrease of $47 million, or 25%, compared to the prior year quarter. ASACOL net sales in North America totaled $128 million and $175 million in the quarters ended June 30, 2013 and 2012, respectively, including net sales in the United States of $122 million and $169 million in the quarters ended June 30, 2013 and 2012, respectively. **The decrease in ASACOL net sales in the United States in the quarter ended June 30, 2013 as compared to the prior year quarter was due primarily to our decision to cease trade shipments of ASACOL 400 mg in the United States as we transitioned from ASACOL 400 mg to DELZICOL in March 2013, offset, in part, by an increase in net sales of ASACOL HD (800 mg).**
> …
> We expect that the loss of ASACOL 400 mg net sales in the United States will be offset, in part, by net sales of DELZICOL and increased net sales of ASACOL HD (800 mg).

(emphasis added) *Warner Chilcott Reports Operating Results for the Quarter Ended June 30, 2013*, *available at* http://globenewswire.com/news-release/2013/07/24/562160/10041663/en/Warner-Chilcott-Reports-Operating-Results-for-the-Quarter-Ended-June-30-2013.html

137. Similarly, at its 2014 Investor Meeting, Actavis (now Allergan), the then-owner of the Asacol franchise, highlighted that the company experienced a loss of sales due to the product hop from Asacol (400 mg) to Asacol HD and Delzocol:



2014 Investor Meeting presentation, *available at* http://phx.corporate-ir.net/External.File?t=1&item=VHlwZT0yfFBhcmVudElEPTUwODA3NDh8Q2hpbGRJRD01MzEyNjY= If Warner Chilcott's product hop did not have the effect of impairing generic competition, the hop would have been a money-losing proposition. The product hop made economic sense for Warner Chilcott solely because the hop did have the effect of impairing generic competition. Warner Chilcott's investments in reformulating and cannibalizing the sales

of Asacol (400mg) were not investments in improving products and helping patients; they were investments in impairing competition.

E. Warner Chilcott Improperly Asserts that the '180 Patent Claims the Delzicol Drug Product

138. Warner Chilcott's putting the bogus capsule around Asacol (400mg) not only prevented generic Asacol (400mg) from being substitutable for Delzicol, it also created the pretext for Warner Chilcott to further abuse the regulatory process by improperly listing a new patent in the Orange Book and then commencing sham patent litigation and obtaining an automatic 30-month stay on competition from generic Delzicol.

139. The cellulose capsule on Delzicol is covered by U.S. Patent No. 6,649,180 ("the '180 patent"), which expires April 13, 2020. Warner Chilcott purports to hold an exclusive license to manufacture Delzicol under the '180 patent. The U.S. Patent and Trademark office originally published the '180 cellulose capsule patent on November 18, 2003. The '180 patent claims a specific "hard capsule formed of cellulose ether film with a specific content of methoxyl and hydroxypropoxyl groups."

140. This patent plainly claims only the empty capsules. It plainly does not claim the Delzicol drug product or any method of using it. Indeed, Warner Chilcott instructs patients that "For patients who are unable to swallow the capsules, the capsules can be opened and the inner tablets swallowed."

141. Nevertheless, as part of its anticompetitive scheme Warner Chilcott listed the '180 patent in the Patent and Exclusivity Information for NDA No. 204412 in the Orange Book, falsely asserting that the patent claims the Delzicol drug product.

142. The FDA does not examine the validity of Orange Book patent submissions, but instead lists in the Orange Book any patents that the NDA-holder claims cover its drug.

143. The drug product for which the Delzicol NDA No. 204412 was approved is a pH-dependent delayed-release product.

144. Asacol (400mg) was a specific controlled-release mesalamine formulation that contained a special acrylic-based resin coating called Eudragit S, which was sold by German pharmaceutical company Evonik Rohm GmbH. Eudragit S was designed to dissolve in alkaline or basic environments – at a pH greater than 7 – such as the intestines, but not to dissolve in acidic environments such as the stomach. The enteric coating allows Asacol (400mg) tablets to pass through the stomach largely intact and then release active mesalamine directly into the affected areas of the colon.

145. As part of the process for approving Delzicol NDA No. 204412, the FDA's Center for Drug Evaluation and Research conducted a clinical pharmacology and biopharmaceutics review, which included a multipoint dissolution profile comparison between Delzicol mesalamine delayed-release capsules, 400 mg, and Asacol mesalamine delayed-release tablets, 400 mg (which did not include a capsule), over a range of pH values, and concluded that the dissolution profiles between the two products are similar over a range of pH values. Therefore, encapsulating the enteric-coated tablet in the Delzicol NDA No. 204412 product has no effect on the pH dependency compared to the enteric-coated Asacol mesalamine delayed-release tablets.

146. The '180 patent claims are limited to a "hard capsule formed of a film composition comprising a hydroxypropyl methyl cellulose as a base, a gelling agent, and a gelling aid."

147. The '180 patent claims do not claim pH-dependent delayed-release capsules. The Delzicol NDA No. 204412 identifies hydroxypropyl methylcellulose ("HPMC") as an inactive

ingredient of each Delzicol mesalamine delayed- release capsule, but does not identify any ingredients that are either gelling agents or gelling aids within the meaning of the '180 patent claims. The '180 patent therefore does not claim the drug for which the Delzicol NDA No. 204412 was approved. Nor does the '180 patent claim an approved method of using Delzicol. Thus, Warner Chilcott improperly listed the '180 patent in the Orange Book under 21 U.S.C. § 355(b)(1)(G) and 21 C.F.R. § 314.53(b)(1).

148. As a result of Warner Chilcott's improper Orange Book listing, no generic manufacturer could submit an ANDA to the FDA seeking approval to market a generic version of Delzicol in the United States without certifying either that its product would not be marketed in the United States until expiration of the listed patent (paragraph III certification) or that each listed patent was invalid or would not be infringed by the proposed product (paragraph IV certification).

149. As noted in detail below, Warner Chilcott's improper patent listing served as the regulatory predicate for it to illegally obtain up to 30 months of protection from generic competition by filing sham lawsuits alleging infringement of the improperly listed patent.

F. Warner Chilcott Files and Maintains Sham Patent Litigation Against Teva In Order to Obtain the Automatic 30-Month Stay of Generic Entry

150. On or about July 16, 2015, Teva Pharmaceuticals USA, Inc. ("Teva"), a generic drug manufacturer, submitted ANDA No. 207873 to the FDA, seeking to market a generic equivalent of Delzicol. This ANDA contained a paragraph IV certification. On or about that same day, Teva sent to Warner Chilcott a Notice Letter as required by the FDCA.

151. Teva attached to its July 16, 2015 letter a detailed statement of the factual and legal bases for Teva's ANDA certifications for the Orange Book-listed '180 patent pursuant to

21 U.S.C. § 355(j)(2)(B)(ii) and an offer of confidential access to relevant portions of Teva's ANDA No. 207873 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

152. On August 14, 2015, Teva, through its counsel, made available to Warner Chilcott's counsel and experts relevant portions of ANDA No. 207873, which establish that the proposed mesalamine delayed-release capsules, 400 mg, for which Teva is seeking FDA approval will not infringe any valid or enforceable claim of the '180 patent.

153. The '180 patent claims a very narrow invention with one independent claim – a specific hard capsule using an HPMC film base with a specific concentration of methoxyl and hydroxypropoxyl groups. The '180 patent does not, and cannot, claim every HPMC capsule. HPMC capsules have been marketed since the 1980s as an alternative to gelatin capsules containing animal byproducts. There are at least 6 HPMC capsules approved for usage by the FDA, and likely other alternative capsules that could be developed and approved by the FDA. Because the capsule offers no therapeutic or pharmacokinetic benefit to the patient, any of these capsules could be used by generic manufacturers without infringing the '180 patent.

154. Despite actual knowledge of the noninfringement, on August 31, 2015, Warner Chilcott filed a patent infringement suit against Teva in the United States District Court for the District of Delaware. 15-cv-00761-UNA. As Warner Chilcott intended when it listed the '180 patent in the Orange Book, this patent infringement action triggered an automatic 30-month stay of final approval of Teva's ANDA. Teva cannot receive final approval to market its product until it either prevails in the patent infringement suit, or the expiration of thirty months, whichever occurs first. Thus, the mere filing of the patent lawsuit -- even though it was meritless -- prevented a generic form of Delzicol from entering the market, thereby illegally extending Warner Chilcott's monopoly.

155. Warner Chilcott's patent lawsuit against Teva is a sham because Warner Chilcott knew that Teva's product does not infringe the patent, and Warner Chilcott brought and is maintaining the lawsuit solely in order to obtain the advantage of the 30-month stay based on its having improperly listed the '180 patent in the Orange Book.

156. As alleged above, Warner Chilcott does not have any good faith factual basis to allege that the proposed product described in Teva's ANDA No. 207873 infringes any claim of the '180 patent, and nevertheless filed and is continuing to maintain the lawsuit.

157. Warner Chilcott filed the patent lawsuit against Teva without regard to the merits of the infringement claims and instead did so for the purpose of delaying Teva's entry into the marketplace by, *inter alia*, burdening Teva with litigation costs and making baseless accusations of infringement causing the approval of Teva's ANDA No. 207873 by the FDA to be stayed.

158. Warner Chilcott's actions amount to an impermissible attempt to prolong the life of its long-standing patent monopoly over its Asacol franchise, including extending the monopoly provided to Warner Chilcott by patents that have already expired.

159. By suing Teva under the Hatch-Waxman Act, Warner Chilcott delayed FDA approval of generic Delzicol capsules by (1) provoking, in effect, a moratorium or a slow track on the FDA's consideration of Teva's ANDA and/or (2) undermining Teva's vigorous pursuit of its application.

160. The FDA receives numerous ANDAs per year and prioritizes those drug applications that are not subject to patent litigation. In the absence of Warner Chilcott's sham litigation, the FDA would focus more attention on Teva's ANDA and would approve it before 30 months.

161. In addition, the sham litigation forced Teva to divert resources away from the FDA approval process and towards defending itself against Warner Chilcott's claim of patent infringement and undermined incentives to obtain rapid FDA approval, since the 30-month stay under the Hatch-Waxman Act has been triggered.

162. Warner Chilcott asserted the frivolous infringement claims in bad faith and with improper purpose – for example, to improperly obtain a 30-month stay of FDA approval of ANDA No. 207873 – thus forcing Teva to undertake the expense of defending the lawsuit and delaying the entry to market of a lower-cost, generic version of Delzicol.

163. Warner Chilcott has thus wielded the '180 patent as an anticompetitive weapon beyond its permissible physical or temporal scope in order to consolidate, entrench, and enhance Warner Chilcott's monopoly and to impair generic competition.

G. Warner Chilcott Files and Maintains Sham Patent Litigation Against Mylan In Order to Obtain the Automatic 30-Month Stay of Generic Entry

164. On or about September 28, 2015, Mylan Pharmaceuticals, Inc. ("Mylan"), a generic drug manufacturer, submitted ANDA 207826 to the FDA, seeking approval to market a generic version of Delzicol in the United States. This ANDA also contained a paragraph IV certification. That same day, Mylan sent the required Notice Letter to Warner Chilcott.

165. On November 9, 2015, Warner Chilcott filed a sham patent suit against Mylan in the Eastern District of Texas. 2:15-cv-01740, claiming infringement of the improperly listed '180 patent. As with the Teva litigation, Warner Chilcott commenced this lawsuit even though it was (1) objectively baseless, in that no reasonable litigant could ultimately expect success on the merits; and (2) motivated by a desire to impose injury on Mylan, a potential competitor and to obtain the automatic 30-month stay, rather than to obtain legal relief.

166. Warner Chilcott does not have any good faith factual basis to allege that the proposed product described in Mylan's ANDA infringes any claim of the '180 patent, and nevertheless filed and is continuing to maintain the lawsuit.

167. Warner Chilcott filed the patent lawsuit against Mylan without regard to the merits of the infringement claims and instead did so for the purpose of delaying Mylan's entry into the marketplace by, *inter alia*, burdening Mylan with litigation costs and making baseless accusations of infringement causing the approval of Mylan's ANDA by the FDA to be stayed.

168. Warner Chilcott's actions amount to an impermissible attempt to prolong the life of its long-standing patent monopoly over its Asacol franchise, including extending the monopoly provided to Warner Chilcott by patents that have already expired.

169. By suing Mylan under the Hatch-Waxman Act, Warner Chilcott delayed FDA approval of generic Delzicol capsules by (1) provoking, in effect, a moratorium or a slow track on the FDA's consideration of Mylan's ANDA and/or (2) undermining Mylan's vigorous pursuit of its application.

170. The FDA receives numerous ANDAs per year and prioritizes those drug applications that are not subject to patent litigation. In the absence of Warner Chilcott's sham litigation, the FDA would focus more attention of Mylan's ANDA and would approve it before 30 months.

171. In addition, the sham litigation forced Mylan to divert resources away from the FDA approval process and towards defending itself against Warner Chilcott's claim of patent infringement and undermined incentives to obtain rapid FDA approval, since the 30-month stay under the Hatch-Waxman Act has been triggered.

172. Warner Chilcott asserted the frivolous infringement claims in bad faith and with improper purpose – for example, to improperly obtain a 30-month stay of any FDA approval of Mylan's ANDA – thus forcing Mylan to undertake the expense of defending the lawsuit and delaying the entry to market of a lower-cost, generic version of Delzicol.

173. Warner Chilcott has thus wielded the '180 patent as an anticompetitive weapon beyond its permissible physical or temporal scope in order to consolidate, entrench, and enhance Warner Chilcott's monopoly and to impair generic competition.

H. Allergan Makes an Unlawful Exclusion Payment to Zydus to Delay Entry of Generic Asacol HD

174. As the anticompetitive scheme unfolded, Warner Chilcott (and then Allergan) found itself at risk from a new threat: imminent AB-rated generic competition for the Asacol HD product.

175. On September 26, 2011, Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Limited filed ANDA No. 203-286 seeking FDA permission to sell a generic version of Asacol HD. Zydus included a Paragraph IV Certification, which meant that it intended to challenge the validity or applicability of the patents on Asacol HD.

176. Within 45 days of receiving Zydus' Paragraph IV Certification, Warner Chilcott filed a patent infringement suit in the District of Delaware, on November 8, 2011. This lawsuit triggered an automatic 30-month stay of Zydus' ANDA for Asacol HD.

177. During the course of the litigation, Actavis acquired Warner Chilcott. Shortly before the parties were set to conduct a bench trial in the District of Delaware, Warner Chilcott decided to remove the possibility of Zydus entering the market for Asacol HD. On December 11, 2013, Warner Chilcott and Zydus entered into an Exclusion Payment Agreement, which they reduced to writing on or about June 7, 2014. Pursuant to that Agreement, Warner Chilcott ended

its patent litigation against Zydus, and Zydus dropped its defenses. At the time of the unlawful agreement, the court hearing the patent case had not issued any substantive rulings regarding the merits of the case.

178. Under the Exclusion Payment Agreement, Zydus agreed to delay marketing its generic Asacol HD until at least November 15, 2015 and possibly as late as June 1, 2016.

179. As the quid pro quo for Zydus' agreement to delay its market entry, Warner Chilcott paid Zydus in the form of a No-AG pledge. The Exclusion Payment Agreement provided that Zydus would delay entering the market until November 15, 2015 if it entered with a product sold under the authority of its own ANDA, and would delay entering the market until June 1, 2016 if it entered with a product supplied to it by Warner Chilcott and sold under the authority of Warner Chilcott's NDA. The Agreement provided that, if Zydus selected the latter option, Warner Chilcott would not compete against Zydus with an authorized generic version of Asacol HD.

180. As Warner Chilcott and Zydus intended, Zydus chose the option that included later entry and the No-AG pledge. By restraining competition between Warner Chilcott and Zydus, that option was far more lucrative for Zydus – at the expense of Plaintiff and other purchasers.

181. By pledging not to market its own authorized generic product, Warner Chilcott enabled Zydus to make double the unit sales, at a much higher price, all at the expense of Plaintiff and other purchasers. The No-AG pledge thus served as substantial payment from Warner Chilcott to Zydus in exchange for its agreement to delay entering the market. Zydus could not have obtained this payment or its equivalent even if Zydus had won the patent litigation against Warner Chilcott.

182. Warner Chilcott made this payment in exchange for Zydus' agreement to delay generic competition to Asacol HD. Absent Zydus' agreement to delay entry into the market with generic Asacol HD, Warner Chilcott would not have agreed to make the payment.

183. The payment is large – it exceeds the amount that Warner Chilcott saved in litigation expenses by settling the patent case with Zydus. Well established literature concludes that litigation of a patent infringement suit of this nature, from complaint to verdict, costs between $6 and $10 million dollars. Warner Chilcott's future expected litigation costs at the time of the settlement with Zydus were much less than that because, among other reasons, the patent case was close to trial at the time of the settlement.

184. A No-AG clause's value to the first-filer is readily calculable using the known economics of the pharmaceutical industry. Warner Chilcott had annual U.S. sales of Asacol HD of $488 million. The difference in revenue for Zydus without a No-AG pact, and with a No-AG pact, is calculated as follows:

a. In the absence of a No-AG clause, Zydus would likely take 80% (or more) of the brand's unit sales. Thus, Zydus would capture approximately $390 million worth of brand units annually ($488 million * 0.8).

b. With only one generic on the market, Zydus would likely price its product at a 10% discount off the brand's price. This would result in generic sales revenues of approximately $351 million annually ($390 million * 0.9).

185. Those revenues would be dramatically lower, however, if Zydus faced competition from an authorized generic. This difference is shown as follows:

a. An FDA study concludes that the addition of a second generic drives the average generic price down from a 10% discount off the brand price to a 48% discount off the brand price. Thus, while generics would still take 80% of brand unit sales, the dollar value of those generic sales here would drop from $351 million to $203 million annually ($390 million * .52).

b. Zydus would not receive all of those revenues, however. Instead, the unit sales of the generic would be split (roughly evenly) between Zydus and Warner Chilcott's authorized generic. In fact, the authorized generic often

captures more than half of the unit sales due to a "first-mover" advantage and other marketing advantages. Without a No-AG clause, Zydus's revenues would be at most $101.5 million annually ($203 million * .5).

c. Thus, with annual brand revenue (before generic entry) of $488 million, the value of a No-AG clause to Zydus is at least $249.5 million annually ($351 million - $101.5 million). That is the amount of the pay-off from Warner Chilcott to Zydus in exchange for its delaying entry into the market.

186. Warner Chilcott's payment to Zydus exceeded the value that it could have obtained *even if it had won* the patent infringement litigation.

187. The value to Warner Chilcott of the No-AG clause is also readily calculable. As demonstrated above, Warner Chilcott could have made at least $101.5 million annually, and likely much more, by marketing an authorized generic version of Asacol HD. The "cost" of the No-AG clause to Warner Chilcott is the value of forgoing those revenues. The value of the No-AG clause to Warner Chilcott, calculated in terms of the value of using the clause to delay generic entry, is even greater. Under the terms of the Warner Chilcott/Zydus Exclusion Payment Agreement, Zydus promised not to enter the market until November 15, 2015 at the earliest -- 23 months after the settlement was announced. By paying off Zydus, the first-filer, Warner Chilcott guaranteed itself at least another 23 months of unencumbered monopoly profits, conservatively estimated to be $935 million.

188. Warner Chilcott and Actavis frequently launched authorized generic versions of their branded counterparts, and have done so with respect to at least the following drugs: Actonel, Actigall, Atelvia, Condylox, Doryx tablets, Emla, Femhrt, Kadian (in at least 7 strengths), Microzide, Norinyl, Nor-Qd, and Tenuate (2 formulations).

189. Warner Chilcott's payment to Zydus guaranteed two distinct periods of non-competition: (a) the period before generic competition, whereby Warner Chilcott and Zydus

allocated 100% of the market to Warner Chilcott; and (b) the period after generic competition, whereby Warner Chilcott and Zydus allocated 100% of the generic segment to Zydus.

190. Defendants have no procompetitive explanation or justification for the payment.

191. But for the agreement between Zydus and Warner Chilcott (now Allergan), both manufacturers would have been incentivized to release dueling generic products; Warner Chilcott would have released an authorized generic product upon Zydus' entry into the market. By agreeing not to compete in the generic sector, Warner Chilcott effectively granted Zydus twice the generic sales it would have otherwise made, and at higher prices.

192. But for the Exclusion Payment Agreement between Warner Chilcott and Zydus, a generic version of Asacol HD would have been available sooner, and when generic competition occurred there would have been at least two generics on the market instead of only one. Plaintiff and other purchasers would have benefitted from the competition.

VI. EFFECT OF THE SCHEME ON COMPETITION AND DAMAGES TO PLAINTIFF AND THE CLASS

193. On October 1, 2013, Allergan plc (then "Actavis") acquired Warner Chilcott plc and became the successor in interest to Asacol (400mg), Asacol HD, and Delzicol.

194. Warner Chilcott's extensive generic impairment efforts have proven beneficial for Allergan. Allergan continues to sell Asacol HD and Delzicol in the United States. Allergan sold approximately $550 million of the two products in 2014. This is hundreds of millions more in sales than Allergan would have achieved absent Warner Chilcott's unlawful scheme to impair generic competition. Generic Asacol (400mg) products would have been priced at a fraction of the cost of brand Asacol HD and Delzicol.

195. Warner Chilcott's (and later Allergan's) overarching anticompetitive scheme impaired and delayed the sale of generic Asacol products in the United States, and unlawfully

enabled Warner Chilcott (and later Allergan) to sell its branded Asacol and Delzicol products at artificially inflated prices. But for Warner Chilcott's (and later Allergan's) unlawful conduct, generic competitors would have been able to compete, unimpeded, with generic versions of Asacol (400mg) products.

196. But for Defendants' anticompetitive conduct, as alleged above, manufacturers of generic Asacol (400mg) tablets would have entered the marketplace and effectively competed with Warner Chilcott on or about July 31, 2013, when the '170 and '171 patents expired, without Warner Chilcott's having switched the market to Asacol HD and Delzicol. As a result, but for Defendants' anticompetitive conduct, Plaintiff and other members of the Class would have: (1) purchased lower-priced generic Asacol (400mg) tablets instead of the higher-priced brand Asacol HD and Delzicol capsules for some or all of their Asacol Franchise Product requirements; (2) paid a lower price for their generic Asacol Franchise Products, sooner; and/or (3) paid lower prices for some or all of their remaining brand purchases.

197. Had Warner Chilcott not reformulated and cannibalized Asacol (400mg) pursuant to the anticompetitive scheme, when generic Asacol (400mg) tablets entered the market they would have been automatically substitutable for most (if not all) of the units of brand Asacol, and all of Warner Chilcott's annual sales of Asacol at that time would have been in 400mg tablet form. Within months, generic tablets would have captured almost all sales at vastly lower prices, delivering substantial savings to Plaintiff and other purchasers. As a result of Warner Chilcott's anticompetitive scheme, however, competition from generic manufacturers has been very significantly impaired.

198. During the relevant period, Plaintiff and other purchasers bought substantial amounts of Asacol HD and Delzicol. As a result of Warner Chilcott's (and later Allergan's)

unlawful conduct as alleged herein, Plaintiff and other purchasers were compelled to pay, and did pay, artificially inflated prices for their Asacol HD and Delzicol product requirements. Plaintiff and the other purchasers paid prices for Asacol HD and Delzicol that were substantially greater than the prices that they would have paid absent the unlawful conduct alleged herein.

199. As a consequence, Plaintiff and other purchasers have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

VII. CLASS ACTION ALLEGATIONS

200. Plaintiff brings this action in its own right and on behalf of all other similarly situated persons and entities under Fed. R. Civ. P. Rules 23(a) and (b)(3), as defined below.

A. Scheme Class

> All persons or entities in the United States and its territories that purchased Asacol HD, Delzicol, and/or generic Asacol HD in any form directly from Warner Chilcott, Allergan, or Zydus, including any predecessor or successor of Warner Chilcott or Allergan, at any time between July 31, 2013 until the anticompetitive effects of Warner Chilcott and Allergan's conduct cease (the "Scheme Class").

201. Excluded from the Scheme Class are Warner Chilcott, Allergan, Zydus, Cadila, and any officers, directors, management, employees, subsidiaries, and affiliates and all federal governmental entities.

202. Members of the Scheme Class are so numerous that joinder is impracticable. Further, the Scheme Class is readily identifiable from information and records in the Defendants' possession.

203. Plaintiff's claims are typical of the claims of the members of the Scheme Class. Plaintiff and all members of the Scheme Class were damaged by the same wrongful conduct by Defendants. Scheme Class members paid artificially inflated prices for brand Asacol HD and

Delzicol formulations as a result of Scheme Defendants' unlawful conduct and were deprived of the opportunity to purchase less-expensive generic drugs.

204. Plaintiff will fairly and adequately protect and represent the interests of the Scheme Class. Plaintiff's interests coincide with those of the wider Scheme Class.

205. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation.

206. Questions of law and fact common to the members of the Scheme Class predominate over questions that affect individual class members because Defendants' conduct affected the entire class similarly.

207. Questions of law and fact common to the Scheme Class include:

a. Whether Scheme Defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic impairment scheme;

b. Whether Scheme Defendants' anticompetitive scheme impaired market entry of generic Asacol (400mg) drug products;

c. Whether Scheme Defendants' reformulation and cannibalization of Asacol (400mg) was predatory and anticompetitive;

d. Whether Scheme Defendants surrounded Delzicol with a capsule for the anticompetitive purpose of impairing generic competition;

e. Whether, regarding those parts of Scheme Defendants' conduct for which justifications may be offered, there were cognizable, non- pretextual, procompetitive justifications, which Defendants' conduct was the least restrictive means of achieving, that offset the harm to competition and consumers in the market in which Asacol (400mg) is sold;

f. Whether direct proof of Scheme Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' monopoly power without the need to also define a relevant market;

g. If markets need to be defined, what are they;

h. Whether Scheme Defendants' scheme, in whole or in part, has substantially affected interstate commerce;

i. Whether Scheme Defendants' scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of Plaintiff and the members of the Scheme Class; and

j. The quantum of overcharges paid by the Scheme Class in the aggregate.

208. Proceeding on a classwide basis is a superior method for the fair and efficient adjudication of the controversy because class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expenses that individual actions would entail. Class treatment will allow injured persons and entities to seek compensation for injuries when it would not be practical for them to do so individually. These benefits substantially outweigh any difficulties that may arise out of class treatment.

209. Plaintiff does not know of any legitimate reason that this action cannot be pursued as a class action.

B. Exclusion Payment Class

> All persons or entities in the United States and its territories that purchased Asacol HD and/or generic Asacol HD in any form directly from Warner Chilcott, Allergan, or Zydus, including any predecessor or successor of Warner Chilcott or Allergan, at any time between December 11, 2013 until the anticompetitive effects of Allergan and Zydus' conduct cease (the "Exclusion Payment Class").

210. Excluded from the Direct Purchaser Class are Warner Chilcott, Allergan, Zydus, Cadila, and any officers, directors, management, employees, subsidiaries, and affiliates and all federal governmental entities.

211. Members of the Class are so numerous that joinder is impracticable. Further, the Direct Purchaser Class is readily identifiable from information and records in the Defendants' possession.

212. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Defendants. Exclusion Payment Class members paid artificially inflated prices for Asacol HD as a result of Defendants' unlawful conduct and were deprived of the opportunity to purchase less-expensive generic Asacol HD.

213. Plaintiff will fairly and adequately protect and represent the interests of the Exclusion Payment Class. Plaintiff's interests coincide with those of the wider Exclusion Payment Class.

214. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation.

215. Questions of law and fact common to the members of the Exclusion Payment Class predominate over questions that affect individual class members because Defendants' conduct affected the entire class similarly.

216. Questions of law and fact common to the Exclusion Payment Class include:

a. Whether Exclusion Payment Defendants conspired to impair generic competition for Asacol HD;

b. Whether, pursuant to the exclusion payment agreement, Allergan made a large and unjustified payment to Zydus;

c. Whether Allergan's payment to Zydus was for a purpose other than delayed entry of generic Asacol HD;

d. Whether any purported procompetitive justifications that Defendants may offer for the payment are cognizable and non-pretextual, and whether an exclusion payment was the least restrictive means of achieving the benefit;

e. Whether Exclusion Payment Defendants' challenged conduct harmed competition;

f. Whether Allergan possessed market power with respect to Asacol HD;

g. Whether Exclusion Payment Defendants' conduct, in whole or in part, has substantially affected interstate commerce;

h. Whether Exclusion Payment Defendants' conduct, in whole or in part, caused antitrust injury through overcharges to the business or property of Plaintiff and the members of the Exclusion Payment Class;

i. The quantum of overcharges paid by the Exclusion Payment Class in the aggregate.

217. Proceeding on a classwide basis is a superior method for the fair and efficient adjudication of the controversy because class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expenses that individual actions would entail. Class treatment will allow injured persons and entities to seek compensation for injuries when it would not be practical to do so individually. These benefits substantially outweigh any difficulties that may arise out of class treatment.

218. Plaintiff does not know of any legitimate reason that this action cannot be pursued as a class action.

VIII. EFFECT ON INTERSTATE COMMERCE

219. Scheme Defendants sold Asacol (400mg), and sold and will sell Asacol HD and Delzicol, across state lines at all relevant times. Exclusion Payment Defendants sold and will sell Asacol HD and its generic equivalents across state lines at all relevant times.

220. Contracts, bills, and other forms of business communications pertaining to Asacol (400mg), Asacol HD, and Delzicol were transmitted in a continuous and uninterrupted flow across state lines in the exchange of interstate commerce.

221. Various instrumentalities were used to effectuate the unlawful acts alleged herein, including United States mail, interstate and foreign travel, and interstate and foreign telephone

commerce during all relevant times. The Defendants' activities, as alleged in this Complaint, have substantially affected interstate commerce.

IX. MARKET POWER

222. With respect to the claims asserted on behalf of the Scheme Class (i.e., the Monopolization claim asserted in Count I and the Attempted Monopolization claim asserted in Count II below), at all relevant times Warner Chilcott and Allergan had monopoly power in the market for Asacol (400mg), Asacol HD, and Delzicol and their generic equivalents (hereafter "Asacol Franchise Drugs") and narrower markets therein, because they had the power to raise or maintain the price of Asacol Franchise Drugs at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

223. Warner Chilcott and Allergan had the ability to control the prices of Asacol Franchise Drugs and exclude relevant competitors. Direct evidence demonstrates that: (a) generic versions of each drug would have entered the market at substantial discounts to the brands but for the Defendants' anticompetitive conduct; (b) the gross margin on each drug was at all times at least 60%; and (c) Defendants never lowered the price of the drugs to the competitive level in response to the pricing of other branded or generic drugs.

224. To the extent that Plaintiff is required to prove monopoly power by defining a relevant product market, Plaintiff alleges that the relevant product market is the market for Asacol Franchise Drugs and narrower markets therein.

225. A small but significant, non-transitory price increase in the price of Asacol Franchise Drugs did not cause a significant loss of sales. At competitive prices, Asacol Franchise Drugs do not exhibit significant, positive, cross-elasticity of demand with respect to price with any other mesalamine formulations or treatments for ulcerative colitis other than AB-rated generic versions of those Asacol Franchise Drugs.

226. Scheme Defendants needed to control only Asacol Franchise Drugs and their AB-rated generic equivalents, and no other products, in order to maintain the price of the products profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Asacol Franchise Drugs would render Defendants unable to profitably maintain supracompetitive prices for those products.

227. Scheme Defendants sold branded Asacol Franchise Products in excess of marginal costs, and in excess of the competitive price, and enjoyed unusually high profit margins.

228. The United States and its territories constitute the relevant geographic market.

229. At all relevant times, Scheme Defendants enjoyed high barriers to entry with respect to the above-defined relevant market due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and AB-rated generic substitution laws.

230. Scheme Defendants' market share in the relevant markets was and remains 100%.

231. With respect to the exclusion-payment claim (i.e., the Sherman Act Section 1 claim asserted in Count III below), at all relevant times Warner Chilcott had market power in the market for Asacol HD and its generic equivalents, because Warner Chilcott had the power to raise or maintain the price of Asacol HD at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

232. Warner Chilcott had the ability to control the prices of Asacol HD and exclude relevant competitors. Direct evidence demonstrates that: (a) generic versions of Asacol HD would have entered the market at substantial discounts to the brand but for the Exclusion Payment Defendants' anticompetitive conduct; (b) the gross margin on Asacol HD was at all

times at least 60%; and (c) Exclusion Payment Defendants never lowered the price of Asacol HD to the competitive level in response to the pricing of other branded or generic drugs.

233. To the extent that Plaintiff is required to prove market power by defining a relevant product market, Plaintiff alleges that the relevant product market is the market for Asacol HD and its generic equivalents.

234. A small but significant, non-transitory price increase in the price of Asacol HD did not cause a significant loss of sales. At competitive prices, Asacol HD does not exhibit significant, positive, cross-elasticity of demand with respect to price with any other mesalamine formulation or treatment for ulcerative colitis other than AB-rated generic versions of the drug.

235. Exclusion Payment Defendants needed to control only Asacol HD, and no other products, in order to maintain the price of the product profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Asacol HD would render Exclusion Payment Defendants unable to profitably maintain supracompetitive prices for the product.

236. Warner Chilcott sold branded Asacol HD in excess of marginal costs, and in excess of the competitive price, and enjoyed unusually high profit margins.

237. The United States and its territories constitute the relevant geographic market.

238. At all relevant times, Warner Chilcott enjoyed high barriers to entry with respect to the above-defined relevant market due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and AB-rated generic substitution laws.

239. Exclusion Payment Defendants' market share in the relevant market was and remains 100%.

X. CLAIMS FOR RELIEF

Count I
Monopolization (15 U.S.C. § 2)
(Against Scheme Defendants Warner Chilcott and Allergan)

240. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

241. At all relevant times, Scheme Defendants possessed substantial market power (i.e. monopoly power) in the relevant market. Defendants possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

242. Scheme Defendants perpetrated an anticompetitive scheme which included, cumulatively and in the alternative, unlawfully:

a. Refusing to reformulate Asacol (400mg) simply by removing DBP, as the FDA had requested, and instead adding a bogus capsule, the purpose of which was to render generic Asacol (400mg) tablets non-substitutable;

b. Withdrawing Asacol (400mg) tablets from the market rather than reformulating them to remove DBP;

c. Causing uncertainty as to whether the FDA would approve any ANDA for generic Asacol (400mg);

d. Cannibalizing the sales of Asacol (400mg);

e. Bribing doctors to switch prescriptions from Asacol (400mg) to Asacol HD;

f. Switching prescriptions from Asacol (400mg) to Asacol HD by promoting the latter for off-label uses;

g. Improperly listing the ’180 patent in the Orange Book;

h. Commencing and maintaining sham patent litigation against Teva;

i. Commencing and maintaining sham patent litigation against Mylan;

j. Paying off Zydus to delay entering the market with generic Asacol HD;

243. Through the anticompetitive scheme described above, Scheme Defendants willfully maintained and continue to maintain monopoly power in the relevant market using restrictive and exclusionary conduct, rather than by providing better products or services, and thereby injured Plaintiff and members of the Scheme Class. Specifically, by denying Plaintiff and members of the Scheme Class the opportunity to purchase Asacol (400mg), Asacol HD, and Delzicol at a substantial discount via generic substitutes, Scheme Defendants willfully maintained their monopoly over (and supracompetitive profits in) the relevant market.

244. Scheme Defendants' conscious objective was and is to continue its dominance of the relevant market by and through the anticompetitive scheme described above.

245. Scheme Defendants' anticompetitive scheme harmed competition and purchasers as alleged above.

246. There are no non-pretextual procompetitive justifications for Scheme Defendants' conduct. Even if there were such a conceivable justification, the anticompetitive effects of Scheme Defendants' conduct far outweigh any conceivable justification. Further, the anticompetitive scheme was far broader than necessary to achieve any conceivable procompetitive benefit.

247. Scheme Defendants' anticompetitive scheme was the direct and proximate cause of the injuries to Plaintiff and the Scheme Class, as described herein.

248. Plaintiff and the members of the Scheme Class have been injured in their business or property as a direct and proximate result of Scheme Defendants' anticompetitive conduct. The injuries include: (1) being denied the opportunity to purchase lower-priced generic Asacol

(400mg), Asacol HD, and Delzicol; and (2) being forced to purchase a more expensive branded Asacol HD, and Delzicol. These injuries are the type that the antitrust laws were designed to prevent, and flow from that which makes Scheme Defendants' conduct unlawful.

249. Plaintiff and the Scheme Class seek damages and treble damages as permitted by law for the injuries they suffered as a result of Scheme Defendants' anticompetitive conduct.

250. Scheme Defendants are jointly and severally liable for all damages suffered by Plaintiff and Scheme Class members.

Count II
Attempt to Monopolize (15 U.S.C. § 2)
(Against Scheme Defendants Warner Chilcott and Allergan)

251. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

252. Scheme Defendants possessed substantial market power (i.e., monopoly power) in the relevant market. Scheme Defendants possessed the power to raise prices, maintain prices, and exclude competitors from the relevant market.

253. Through the totality of the scheme described above, Scheme Defendants willfully maintained and continue to maintain monopoly power in the relevant market using restrictive and exclusionary conduct, rather than by providing better products or services, and thereby injured Plaintiff and members of the Scheme Class.

254. At all relevant times, Scheme Defendants had a specific intent to achieve or maintain a monopoly in the relevant market.

255. Scheme Defendants' actions were intended to suppress rather than to promote competition on the merits and have had precisely the intended effect.

256. Plaintiff and the members of the Scheme Class have been injured in their business or property as a direct and proximate result of Scheme Defendants' unlawful attempted monopolization. These injuries are the type that the antitrust laws were designed to prevent, and flow from that which makes Scheme Defendants' conduct unlawful.

257. Plaintiff and the Scheme Class seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Scheme Defendants' anticompetitive conduct.

258. Scheme Defendants are jointly and severally liable for all damages suffered by Plaintiff and Scheme Class members.

Count III
Agreement Restraining Trade (15 U.S.C. § 1)
(Against Exclusion Payment Defendants Allergan and Zydus)

259. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

260. After two years of litigation related to the patents ostensibly covering Asacol HD, Allergan (then "Actavis") and generic competitor Zydus entered into an exclusion payment agreement under which Allergan agreed to pay Zydus substantial consideration —*i.e.*, a "large and unexplained payment" of at least $249.5 million annually in the form of a no-authorized generic agreement —in exchange for Zydus' agreement to delay in marketing its generic version of Asacol HD. The exclusion payment far exceeded any reasonable estimate of Allergan's saved litigation costs in the underlying patent case. The purpose and effect of the exclusion payment agreement were to:

a. Allocate 100% of the Asacol HD market to Allergan;

b. Prevent Zydus from selling a generic equivalent of Asacol HD in the United States until at least November 15, 2015;

c. Prevent Allergan from competing against Zydus with an authorized generic version of Asacol HD once Zydus launches its generic product; and

d. Effectively fix the price that Plaintiff and members of the Exclusion Payment Class would pay for Asacol HD brand and generic prescriptions at supracompetitive levels.

261. The exclusion payment agreement was the direct and proximate cause of harm to Plaintiff and the Exclusion Payment Class as set forth above.

262. There is and was no legitimate, nonpretextual, procompetitive business justification for the exclusion payment that outweighs its harmful effect and that could not have been accomplished through less restrictive means.

263. By engaging in the foregoing conduct, Exclusion Payment Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of 15 U.S.C. § 1.

264. Plaintiff and the members of the Exclusion Payment Class have been injured in their business or property as a direct and proximate result of Exclusion Payment Defendants' anticompetitive conduct. The injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Asacol HD; (2) being forced to purchase a more expensive branded Asacol HD; and (3) being deprived of the benefit of competition from an authorized generic version of Asacol HD. These injuries are the type that the antitrust laws were designed to prevent, and flow from that which makes Exclusion Payment Defendants' conduct unlawful.

265. Plaintiff and the Exclusion Payment Class seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Exclusion Payment Defendants' anticompetitive conduct.

266. Exclusion Payment Defendants are jointly and severally liable for all damages suffered by Plaintiff and Exclusion Payment Class members.

XI. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of itself and the Classes, respectfully requests that the Court:

a. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Classes, and declare the Plaintiff as the representative of the Classes;

b. Enter joint and several judgments against Defendants and in favor of Plaintiff and the Classes;

c. Award the Classes damages (i.e., three times overcharges) in an amount to be determined at trial;

d. Award Plaintiff and the Classes their costs of suit, including reasonable attorneys' fees as provided by law; and

Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XII. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiff on behalf of itself and the proposed Classes, demands a trial by jury on all issues so triable.

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